Statement of Dr. Henry B. Steele made on Behalf of the Government of The Province of Alberta before the Special Committee on Drug Costs and Prices of the House of Commons, on Tuesday, February 14, 1967

I must begin by apologizing for the length of this submission and for the relatively lengthy statement necessary to summarize it. When asked by the Government of the Province of Alberta to prepare this submission, I learned by recourse to the orders of reference of this Committee that it was resolved "That the Committee be empowered to consider and recommend, as it may deem expedient, respecting a comprehensive and effective program to reduce the price of drugs." The presentation of a comprehensive program to reduce drug prices necessarily requires a lengthy document. Furthermore, very few of the briefs presented before this Committee have dealt directly and consecutively with the economies of the drug industry--that is, with drug costs and prices as such. In fact, the Consumers' Association of Canada is the only group which proposed an integrated program of economic reforms aimed at the reduction of drug prices. Under these circumstances, I felt that the submission of the Government of the Province of Alberta could best be devoted to a detailed analysis of the economic factors affecting drug supply and demand, and hence drug prices, and to the development of a group of recommendations designed to permit a reduction of drug prices.

By how much can the price of drugs be reduced? It is interesting that the orders of reference for this Committee take it for granted that drug prices are too high, since they simply contemplate the recommendation of an effective program to reduce the price of drugs. To determine whether drug prices are too high, and hence can and should be reduced, it would be desirable to compare present drug prices with the prices which would be charged by drug firms in an efficiently competitive drug industry. Under efficient competition, prices would be just sufficient to cover costs of production and distribution, plus a rate of return on investment which is no higher than is necessary to elicit the required capital investment.

But how can one estimate the prices which would be charged by an efficiently competitive drug industry? For the most part, only indirectly. The production costs for individual drug

produced by the major firms should cast more light on the matter than any other set of data--if only these could be obtained. Since the Committee did not obtain and publish data on drug production costs of the major firms, one has only the choice of using the best available substitute data, or of speculating in an economic vacuum.

The former alternative seems preferable. Consequently, cost-price comparisons have been made, wherever possible, by comparing recent Canadian drug prices with two types of cost data. First, recent drug prices can be compared with current drug production costs, to the extent that statements have been made by witnesses appearing before this Committee which identified certain costs or at least permitted some approximation of their magnitudes. Unfortunately, there are only a very few such instances. Second, recent Canadian drug prices may be compared with Canadian drug costs as reported in the Green Book, which is the only publicly available source of any Canadian drug cost data. Since these cost figures date from around 1960, however, it is likely that some loss of comparability is associated with their use, although the degree of such loss cannot be determined. Moreover, the data in the Green Book refer frequently not to actual factory costs, but to prices paid for the imported bulk chemicals. Since many of these bulk chemicals were imported from United States parents of Canadian subsidiaries, one may consider the reported Canadian import and production costs in conjunction with the computed costs of the same drugs as calculated for the United States producers by the Kefauver Subcommittee staff, in those few instances where such data is available for the same drugs at about the same period in time.

A comparison of prices and estimated costs for all the drugs for which any basis for making comparisons exists, indicates that the ratio of production costs to prices ranges very roughly from about five per cent to about twenty-five per cent of the price received by the manufacturer on sales to wholesalers. There is some clustering of the observations in the ten to fifteen per cent range. This is an unusually low ratio of production cost to price received.

The Pharmaceutical Manufacturers Association of Canada has presented evidence on the breakdown of the manufacturer's sales dollar, which shows that about 30 per cent went to

manufacturing costs. This does not refer to any individual product, but to the average for all products included in the PMAC survey. Since this ratio is about twice the average cost estimated for the group of single drugs considered just above, one wonders about the discrepancy. It is possible that the drugs in the former group had a ratio well below the average of all prescription drugs, but it is also possible that the PMAC calculations average in the experience of all sorts of products sold by drug firms, and do not segregate packaged prescription pharmaceuticals for human use from bulk drug sales, veterinary products feed supplements, and other lower profit margin items with which the Committee is not as directly concerned.

A breakdown between human pharmaceuticals and other products is available for the computation of the cost of goods sold, however, and the ratio of cost of goods sold to sales is about 33 per cent, for 1964. This is strikingly low in relation to the ratio of 73.7 per cent for the average of all Canadian manufacturing firms as shown by the 1962 Dun and Bradstreet of Canada survey introduced into the record of this Committee. For all manufacturing firms, the equivalent markup of total price over cost of goods sold is approximately 36 per cent (i.e., the gross margin of 26.3 per cent divided by 73.7 per cent), while the markup for drugs is 203 per cent. If we assume that manufacturing firms in Canada are on the whole workably competitive, their average markup of 36 per cent might be applied to the 33 cents in the drug sales dollar which is accounted for by the cost of goods sold. The resulting markup would add about 11.9 cents to the cost of goods sold of 33 cents, bringing the price up to about 45 cents. Hence, very roughly speaking, the ability of the drug industry to raise itself above the necessity price for competition has enabled them to charge $1.00 for selling at wholesale a product the average cost of goods sold input of which is only 33 cents. If they were subject to the same competitive market pressures as the average manufacturing firm in Canada, they would have to be content with charging only 44.9 cents for 33 cents worth of cost of goods sold. Even if we raise the figure to 50 cents, the price of drugs in Canada is still indicated as being twice as high as it might be in the presence of more adequate competition.

What factors are responsible for permitting a gross margin of 67 per cent in drugs while all manufacturing companies have to be content with only 26.3 per cent? Here is where elementary economic analysis is useful in illuminating the relationship between supply, demand, and prices. Because of the great urgency of the need for medication, demand is almost completely insensitive to prices charged. There is no economic reason why low prices should be charged just because production costs are low, when a price which is for example ten or twenty times as great as production costs will not significantly reduce the amount purchased. Broadly speaking, prcies are determined almost entirely by the urgency of demand, and ordinarily have extremely little to do with the costs of production. Hence there is no real reason to lower prices if costs should decline, and conversely there is not much room for increasing prices if costs should rise, since prices have presumably been set initially at the profit maximizing level relative to demand.

Drug industry economics are such that only perhaps about 30 cents out of every sales dollar of cash flow has to be devoted to factory costs of production. What governs the disposition of the remaining seventy cents? Firms apparently find it necessary to dissipate about 30 cents of each sales dollar in sales promotion efforts, which arguably are largely mutually offsetting as among firms, the emphasis being on persuading the prescribing physician rather than on simply informing him. About seven cents is spent on research and development, largely applied research and product development. In drugs, as in other chemicals industries research is rationally viewed as a means of implementing a profitable marketing operation, hence the share of the research budget devoted to truly fundamental research is understandably small. Between 4 and 15 cents in the sales dollar goes to distributing and warehousing costs and to actual outlays for manufacturing administration. The ambiguity arises here because it was never made explicit to the Committee how much, if any, of the eleven cents in the sales dollar which was designated as costs of manufacturing administration was accounted for by management fees assessed against Canadian subsidiaries by foreign parents. This leaves between 18 and 29 cents in the sales dollar for profits before taxes, royalties, and management fees. This sum represents the pre-tax residual receipts of the drug firm after allowing for actual

expenditures. While intra-company management fees and royalties may indirectly relate to certain actual costs of administration and research, the arrangements by which these fees are determined do not reflect the discipline of an arms-length market transaction. And royalties paid are generally not in any way systematically related to past or future research costs, but instead partake more of the nature of a levy on the expected profits to the licensee from the exploitation of the patent license. In other words, intra-company management fees and royalties represent imputations of portions of the surplus of revenues over actual costs, and it makes a lot of difference to the buyer whether the profits of the Canadian subsidiary are imputed away or competed away.

Hence the sales dollar breaks down roughly into 30 cents for manufacturing plus a maximum of 15 cents for distribution and manufacturing overhead. The remaining 55 cents is the subject of discretionary disposition to a greater degree. About 7 cents is devoted to the quasi-marketing functions of development and research, about 30 cents is spent in sales promotion, and a minimum of 18 cents remains for profits after taxes, royalties paid to others and intra-company imputations regarding royalties and management fees.

This is the quantitative breakdown of the sales dollar as presented to this Committee by PMAC, but it differs considerably from the qualitative impression created drug firm spokesmen both in their appearances before this Committee and in their public relations activities generally, where the height of drug prices is attributed to the magnitude of the research budget and the costs of quality control. Since research and development combined amount to only about 7 cents in the sales dollar, and since quality control costs--to the extent that it is meaningful to isolate them--add only one or two more cents, it is apparent that drug prices are being explained or defended in terms of factors accounting for less than ten per cent of the total price.

Since the basic cause of high drug prices in Canada is the lack of price competition, both among major drug manufacturing firms and among retail druggists, it is appropriate to ask what reforms are necessary to institute price competition at all levels of the industry and thus lower drug prices. Each of the recommendations made in this Submission will be stated and briefly discussed.

A. Recommendations pertaining to patent and trade mark reform.

Drug buyers in Canada are fortunate in that drug product patents may not be obtained independently of process patents, and that such patents are subject to compulsory licensing under normal circumstances. In contrast, drug patent protection is absolute in the United States. Why, then, have Canadian drug prices often reached higher levels than are charged in the United States? There are four respects in which the present state of Canadian patent law contributes to high drug prices. First, relatively few applications have been made for compulsory licenses, and none of the firms which have been granted licenses have been truly major factors in the industry. Second, applications for licenses to import patented drugs have been refused. Third, since the products of firms selling under compulsory licenses are usually marketed under generic names, or under little-advertised brand names, the burden of securing a market in competition with the highly promoted brands of major firms, taken in conjunction with the habit of brand name prescribing and the atmosphere of disparagement of generic name products created by brand name sellers, puts even the successful applicant for a compulsory license in at best an inferior position in the market. He may undercut his rivals by selling at prices only a tenth as high as theirs, and yet not be able to gain even a tenth of the market. Such an outcome would be unthinkable in any sort of truly competitive market, and must be attributed to sales promotion and prescribing practices, which are supported by patent protection in general in spite of occasional compulsory licenses. Fourth, if a firm produces or imports a drug which is covered by a Canadian process patent, the burden of proof is on the producer or importer to show that the drug was produced by a non-infringing process, and the costs and hazards of litigation may easily deter such production or importation.

To further reduce existing patent-related barriers to new competition in the drug industry, the following recommendations are made:

1. Compulsory licenses to import patented drugs should be granted, subject to the payment of reasonable royalties. These licenses should provide for the importation of semi-finished and finsihed dosage forms as well as bulk drugs.

2. Section 41(2) of the Patent Act should be amended to put the burden of proof of infringement of drug process patents on the plaintiff.

3. Every effort should be made to further expedite the process of acting upon compulso license applications. If reasonable expedition cannot be achieved, such licenses should be issued as of right.

Two further recommendations relate to patents and trade marks.

4. Section 19 of the Patent Act should be amended to allow provincial governments and their agencies as well as the Government of Canada to use any patented drug, subject to the payment of reasonable compensation.

This recommendation of the Hall Commission is highly appropriate since it would further safeguard the Canadian drug buyer against restriction of supply and high prices.

5. The Trade Marks Act should be amended to allow in general the importation of trade-marked drugs which have been produced by a company related to the company possessing the Canadian trade mark.

The securing of this reform would make it possible for independent Canadian wholesalers to buy drugs from wholesalers in, for example, the United States, and sell the drugs in Canada at a lower price than that charged by the Canadian subsidiary of the United States manufacturer, provided that the difference in prices between the two countries is greater than the import duty payable. At present the owner of a Canadian trade mark is permitted to monopolize the importation and distribution of any product bearing this mark, whether or not any production of the product is carried on in Canada. If the proposed amendment were adopted, the only direct retaliation would consist in having the Canadian subsidiary take out a new trade mark for its drug, but it would hesitate to do so to the extent that sales promotion efforts in both the Canadian and United States markets had made the trade-marked name itself a valuable business asset, the changing of which would occasion a capital loss.

B. Recommendations Pertaining to Tariffs and Anti-Dumping Laws.

Three recommendations are made which relate to import duties on drugs.

6. The schedule of tariffs on drugs should be reviewed by the Tariff Board, with a view toward:

(a) Limiting the liability of drugs to tariff duties to those drugs of a class or kind actually made in Canada, and

(b) reducing applicable rates to the minimum level consistent with the provision of the desired degree of protection of domestic producers.

Tariffs are intentionally designed to protect domestically situated producers by imposing an import tax burden on foreign goods. Except perhaps in the very long run, tariffs tend directly to increase domestic prices by encouraging higher cost domestic producers at the expense of lower cost imports. Hence the complete elimination of drug tariffs would be the most expedient tariff measure for maximizing the potential decrease in Canadian drug prices. But if it is desired to retain protection for domestically situated producers, the customs laws should be such as to give protection only to those drugs which are actually being produced in the country at any given time. This could be done by limiting tariff protection to drugs of a class or kind actually being made in Canada, but care should be taken to avoid defining "class" too broadly. Rather than regarding all antibiotics as belonging to a certain class and hence applying tariffs to all antibiotics if even a single antibiotic is produced in Canada, it would be preferable, if feasible, to maintain an exhaustive current enumeration of all drugs which are close therapeutic substitutes for drugs made in Canada, and to exempt from tariffs any drugs not on the list. This would not prevent the establishment of new domestic drug plants since tariffs would become applicable to imports of any drugs of a class or kind produced by domestic plants as soon as Canadian production were to be established.

7. Liability to anti-dumping duty should be limited to drugs of a kind actually made in Canada, where "kind" is defined in terms of the active ingredient.

The existence of the anti-dumping duty tends to motivate foreign parents of Canadian subsidiaries to impute a larger share of total profits to the parent by setting prices to the subsidiary at levels high enough to avoid all possibility of being subject to the anti-dumping duty. While abolition of the anti-dumping duty would eliminate this particular

parent-subsidiary complication, this would expose domestic producers to the threat of dumping. A preferable expedient would appear to be the limitation of anti-dumping duties to drugs of a kind actually made in Canada. At present, while most of the pharmaceutical drugs used in the preparation of dosage forms in Canada are not themselves made in Canada, most pharmaceutical preparations containing these pharmaceutical drugs are considered to be of a class of kind for dumping duty purposes. Hence although the active ingredients in a drug are not manufactu... in Canada, dosage forms containing these drugs may be subjected to anti-dumping duty which protect sellers of dosage forms but do not afford protection to domestic manufacturers since the drug is not being domestically produced. Drug prices may therefore be increased by the amounts of anti-dumping duty paid, or by the increase in invoice prices necessary to eliminate the danger of anti-dumping duties, not only for drugs made in Canada, but also for all other drugs of a general class made in Canada. Limiting the application of anti-dumping duties to drugs of a kind made in Canada would therefore eliminate the possible price-increasing effects of measures taken to minimize the likelihood of liability for payment of anti-dumping duties for all drugs of the same class sold in Canada.

8. The valuation for customs purposes of imported drugs should be based on production cost plus a maximum allowance for gross profit (or on invoice cost, if higher) in situations where it is not possible independently to ascertain fair market value.

The reduction in the scope of anti-dumping duties would eliminate many of the instances in which valuation problems for imported drugs arise. The goal of valuation of those imported drugs still subject to dumping duties at levels which are not so high as to motivate foreign parents of Canadian subsidiaries to take too large a portion of the combined profits of parent and subsidiary in the foreign country, would be most expeditiously arrived at by setti... this value equal to production cost plus an allowance for gross profit. To simlify administration, a reasonable maximum allowance for gross profit should be stipulated, as is now done for some items of import, such as the 5 per cent allowance for imported car parts of a class or kind not made in Canada. If after appropriate study a maximum rate of for example ten per cent were to be adopted for drugs, the motivation to charge high prices to

Canadian subsidiaries to avoid anti-dumping duties would be removed. If a drug cost $1.00 to produce, invoice costs need be no more than $1.10 to avoid all liability to dumping duty.

9. The federal sales tax on drugs should be removed.

Since demand for drugs is almost completely insensitive to price levels, the imposition of an eleven per cent sales tax at the manufacturer's level will be pyramided upward through distribution channels and the increase in price to the consumer will range up to a maximum of eleven per cent, depending upon the pricing policy of the retail druggist. (See Appendix A to this Submission for detailed calculations.) But it does not follow that the removal of the sales tax, in itself, would result in corresponding price reductions. Only in a highly competitive market can one safely make the assumption that reductions in taxes or cost levels generally will be passed forward to the customer in full in the form of lower prices. Sales tax abolition must be only one part of a comprehensive reform program to introduce genuine price competition into the drug industry.

10. The Food and Drug Directorate should be provided with sufficient authority, funds, and staff to enable it to carry out an inspection program adequate to prevent the marketing of substandard drugs and establish confidence in all drugs sold in Canada.

It is of extreme importance that public inspection of drugs be made adequate enough to establish confidence in the quality of all drugs on the market, for only under these circumstances can domestic and imported generic drugs compete with brand name drugs on a price basis. Dr. R. A. Chapman, Director-General of the Food and Drugs Directorate, has recently stated before this Committee that even under present inspection levels, there does not seem to be any significant difference between the quality of generic and brand name drugs sold in Canada, whether the drugs were domestically produced or imported. Although this Committee would seem to be concerned predominantly with issues of drug economics, it is fair to say that on many occasions its concern for drug safety has prevented a sufficiently sharp focus on the economic issues. It has been said that one cannot divorce questions of safety from questions of cost. The obvious way to proceed is simply to compute the full cost of

insuring safety, taking into account both the public cost and the increase in private costs to be passed on to consumers. Against these costs one should weigh the twofold benefits of the elimination of both inferior brand name and generic drugs, and the pressures for price reduction which will develop when generic drugs are seen to be of equivalent quality with brand name drugs, but of much lower price. There is no doubt in my mind that the cost savings alone from lower drug prices would repay many times the added expense of expanded inspection. For example, from available information it appears that in the United States in 1958 an adequate inspection program would have paid for itself even if the resulting price reductions for brand name drugs had been as little as one-quarter of one per cent. Similar data for Canada are not at my disposal, but I doubt if the order of magnitude of required cost reductions is greatly dissimilar between the two countries.

11. Unnecessary barriers to the marketing of new drugs by additional firms should be eliminated. Where a new drug has been cleared for marketing on the basis of adequate data compiled by an original applicant, the same drug should be approved for marketing by any firm capable of producing the identical drug. Similarly, unnecessarily onerous burdens in the way of supplying drug information which merely duplicates existing known information should not be imposed.

The emphasis in this recommendation is upon avoiding truly unnecessary barriers and burdens, which unnecessarily prolong the monopoly power period of the patent holder. I am in favor of safety, but I am also a believer in economy and am opposed to requirements which involve wasteful duplication of effort in busy-work which accomplishes nothing which has not already been done.

12. The publication of a governmentally sponsored newsletter evaluating drugs, similar to the Prescriber's Journal in Great Britain should be considered, particularly if widespread subscription by Canadian physicians to presently or prospectively published independent newsletters of this type fails to develop.

If vigorous price competition is injected into the drug market the ability of major firms to finance sales promotion will decline greatly. To the extent that this eliminates merely persuasive sales appeals and reduces excessive competition for the attention of the

physician, the results will be salutary. It is moreover desirable that independent publications develop to supplement the informative releases of individual firms, and to completely supplant the purely persuasive promotional materials. It is to be hoped that physicians would voluntarily subscribe to independent newsletters. But the experience of the Medical Letter in the United States is not encouraging--only about 15 per cent of physicians have subscribed. If similar apathy is betrayed by Canadian physicians, the publication and distribution of such a newsletter at public expense may be necessary, as in the United Kingdom.

13. Every reasonable effort should be made to inject more price competition into drug retailing. Serious consideration should be given to the liberalizing of the requirements for operating drugstores and dispensing prescriptions, so that the development of lower priced outlets for drugs such as discount pharmacies and mail order drug houses can be encouraged.

Too little attention has been devoted to the role of the retail druggist in the overall level of drug prices. The conclusion reached in the Green Book is that price competition among retail druggists is distinguished by its almost complete absence. If and when price competition among drug manufacturers is brought about, the full benefits of lower prices at the manufacturers level and of the hopefully more widespread practice of generic prescribing, will not be realized unless drug retailing also becomes more competitive. Since this situati[illegible] prevails even after resale price maintenance has been outlawed, the problem appears to be a deep-seated one. Its solution must await the adoption of the maximum practical liberalizatio[illegible] of the traditional restrictions limiting entry into drug retailing. This liberalization shou[illegible] be such as to constitute recognition that the traditional pharmacist's distinctive functions are being altered away from professional competence in compounding and toward skills in merchandising. This more than anything else would probably bring about new entry into the market by those who are not traditionally opposed to price competition. In many lines of trade, sellers were inefficient and distribution methods stagnant until competition develope[illegible] from sources such as supermarkets and mail order houses. Drug "supermarkets" or discount h[illegible] are by their nature better suited to large urban centers, but the encouragement of mail order

pharmacy, where feasible, would do much to spur competition in more thinly settled areas where druggists may have local monopolies.

14. If the above reforms do not succeed in reducing drug prices to competitive levels in a reasonable period of time, drug patents in Canada should be completely abolished.

In its Report, the Restrictive Trade Practices Commission recommended the abolition of drug patents. The Hall Commission was more sensitive to the possible adverse effects upon Canada of retaliation by nations committed to drug patents, and recommended retention of drug patent privileges, modified only by the provision for compulsory licenses to import, during a trial period during which the effect of various reforms on price levels would be observed. This recommendation appears to be very appropriate.

HOUSE OF COMMONS

First Session — Twenty-seventh Parliament

1966

SPECIAL COMMITTEE

ON

DRUG COSTS AND PRICES

SUBMISSION

of

THE GOVERNMENT OF THE PROVINCE OF ALBERTA

bruary, 1967.

CONTENTS

CHAPTER I

INTRODUCTION

My name is Henry B. Steele. I am associate Professor of Economics at the University of Houston, Houston, Texas.

I am delighted to have the opportunity of making this presentation on the behalf of the Province of Alberta. I am an academic economist and have been engaged in studies of drug industry economics and policy problems during the last six years. I have written three articles on drug industry economics and regulation (10, 11, 12)[1] which have appeared in professional economics journals, and I am currently writing a book on drug industry economics and regulation. I have also written papers on the supply and distribution of physicians' services (22, 23). In my research I have been continually hampered by lack of precise and authoritative data on drug costs and prices, the subject of the present inquiry by your Committee. In fact, the only evidence of any sort regarding drug costs has been provided as a result of governmentally sponsored investigations. I have studied all the publicly available records, hearings, and reports, to date, of drug investigatory bodies in both the United States and Canada, as well as much of the material from the United Kingdom. Much useful information has been presented regarding the Canadian drug industry. Nevertheless, I am continually forced to resort to the data on United States drug production costs as of about 1960, whenever it is necessary to draw conclusions regarding the relationship of drug prices to production costs. While these figures relate to very important drugs, it is unfortunate that they relate to only a few drugs, that they relate to a period now several years in the past, and that they relate to the United States rather than to Canada.

An investigating committee charged with the responsibility of studying drug costs and prices certainly needs to be provided with

[1] Numbers in parentheses appearing throughout this submission designate the appropriate sources in the List of References which follow the Appendices.

concrete statistical information on computed costs and methods of cost allocation by the companies producing drugs. In its submission to the Royal Commission on Health Services, February 12, 1962, the Province of Alberta reprinted a chart from the Report of the Subcommittee on Antitrust and Monopoly of the Committee of the Judiciary of the United States Senate hereafter referred to as the Kefauver Subcommittee showing factory cost, royalties, and gross margin above production costs for producing tetracycline capsules by Upjohn and Bristol, with the comment:

> ".....we might well ask the question: If the records of Upjohn and Bristol enabled the Kefauver Committee to put this information concerning revenue cost spreads on the public record in the United States, why is it considered so objectionable to put the same information upon the public record in Canada?"

(3a) The question is as relevant today as it was in 1962. In all fairness, it should not be suggested that obtaining this cost data is an easy task; the chief reason why it is difficult for public bodies to insist upon being supplied with such data is the sturdiness of the "trade secret" dogma--that it would put firms at a disadvantage to have their cost data made public for the edification of their rivals.

In this application, the "trade secret" dogma probably has somewhat different roots than are generally put forth. I have been teaching courses, conducting research, and doing consulting work in the areas of industrial organization and the public regulation of industry for over ten years, and I have become convinced that major firms in many industries are able to inform themselves with reasonable accuracy as to the approximate cost conditions under which their rivals produce. I admit that this is a general impression based on accumulated experience rather than on documentary proof. Nevertheless, it is a very consistently confirmed impression. Hence it strikes me that only in a limited sense are production cost statistics "trade secrets," the revelation of which would damage the firm's ability to maintain its share of the market with respect to its rivals. This is particularly true in the drug industry

since such disclosure is of crucial interest to competitors only if they wish to engage in rather sharp price competition, and the drug industry is not notorious for severity of price competition. Above and beyond this, however, there is without doubt an intense reluctance on the part of the firm to release data which would confirm the surmises of rivals regarding one's cost position. There may be a certain illusion among firms such that while the firm has a good idea of its rivals' costs, it regards the secrecy of its own as being better established. I believe this to be an illusion on the part of the firm, and I suggest that while it may be generous to be chartible to the illusions of the producers, it is socially much more useful to obtain and make public all the facts in the matter. After all, if a subject is to be investigated, the materials with which it is concerned must be identified and evaluated.

On the other hand, producers may more often have valid reasons for objecting to the disclosure of their costs on grounds that it may be edifying to consumers, rather than to rival producers. There may be reasonable grounds for such reluctance. Variable costs may be small relative to total costs. The nature of capital costs may not be understood clearly by the public. Informed opinions as to reasonable rates of profit may vary; uninformed opinions vary even more widely. The nature of risks faced may not be understood. The relationship of risks to an appropriate rate of profit is a very complex matter. Finally, there may be an irrational hostility to profit as such, regardless of the rate of return on investment. Despite all this, the facts should be made known, particularly in view of intense and widespread public concern over drug prices. The industry certainly has command of resources which allow it to defend itself; it is only fair that the public be supplied with the facts which will enable policy makers to determine whether or not the economics of the drug industry are in fact defensible.

At present, however, a student of the cost and price relationships in the Canadian drug industry has no adequate source of information to allow him to reach definite and comprehensive conclusions. This is true

regardless of whether he has been conducting his studies in Toronto, Texas, or Taiwan. Considerably more information is available on cost-price relationships in the United States drug industry as of the early 1960's. To what extent is one justified in extrapolating cost data from the United States into the Canadian market? In the absence of definitive Canadian cost data, the question cannot be answered. It would appear to be incumbent upon Canadian producers to demonstrate that the comparisons are significantly in error, by producing definitive computations of their current cost situations. Otherwise, it is clearly preferable to base conclusions on objective data, even if of limited relevance, than to speculate completely in a vacuum.

It is not proposed that United States market data will be substituted en masse for Canadian; where Canadian data is available it will be employed. Where market circumstances differ between the two countries, attempts will be made to allow for such differences. Actually, the similarities between the drug industries in the two countries are much more striking than the differences. This is also the finding of the Restrictive Trade Practices Commission:

> "Conditions in the drug industry in Canada are related to and are influenced by conditions in the industry in the United States; in fact, in many respects the Canadian market may be considered as simply an extension of the United States market."

(2a) Since Frosst was acquired by Merck in 1965, no Canadian drug firm of any size has remained under Canadian control. About 90% of the Canadian drug industry, it is well known, is controlled by foreign investors, and although relative sales volume data for individual firms is not available, it is clear that the majority of the market is controlled by subsidiaries of American firms. Furthermore, some European-based firms are major factors in both the United States and the Canadian markets. According to the Pharmaceutical Manufacturers Association of Canada brief, 36 of its 57 member firms are based in the United States. I am at present unable to confirm how many, if any, of their members are Canadian-owned; the number would appear to be from three to six. (6a)

The major firms which have testified before this Committee have been unanimous in characterizing the drug industry as an international industry, in the world-wide context of which the Canadian market must occupy a secondary position because of its small size. There is no doubt that the United States market is by far the world's most important because of its large size and high per capita income. Because of the absolute character of patent protection in the United States, the size of its market is all the more attractive, and it is obvious that this patent protection, coupled with high domestic demand, acts to increase the level of world drug prices as a whole. Not only is the United States the most attractive location for a drug manufacturer, but the prospect of obtaining a U.S. drug product patent must be a potent incentive for a particular type of research in other countries where absolute patent protection is not granted. United States patent protection provides the basis for both directly and indirectly limiting competition in both United States and world markets by making the spontaneous or independent development of price competition anywhere in the world to some extent less likely. (Similarly, the absence of the patent privilege for drugs in Italy has to some extent made for greater price competition not only domestically, but throughout the world.) It is thus to some extent Canada's misfortune to be in such close proximity to the world's most lucrative drug market; the high prices south of the Canadian border are not only preserved when the border is passed, but apparently are in most instances actually magnified. There may be a few valid economic reasons why prices might be higher in Canada. There would be certain downward pressures created on Canadian prices if United States drug prices could be reduced. The present problem, however, is to attempt to reduce those Canadian drug prices which may be unreasonably high, by unilateral action by Canada. Unfortunately, both the ways in which the Canadian market is related to, and separated from, the United States market, tend to keep Canadian prices high. Since the present discussion is merely devoted to illustrating the ways in which United States drug industry economics are

relevant to Canadian drug industry economics, the specific details of these interrelationships will be reserved for later discussion at the appropriate times. To summarize the similarities and differences between the drug industries in the two countries, the following tabulation may be instructive:

A. Similarities:

1. The same firms do the great majority of ethical drugs sales in both countries. About 80% of the active ingredients in drugs sold in Canada are imported in bulk form, the great majority of these coming from the United States, and hence produced under United States cost conditions.

2. Tabletting, bottling, and other costs associated with the conversion of the bulk active ingredient into finished dosage forms, are minor factors in total cost and these costs should not vary greatly between the two countries.

3. Outlays for other purposes than production costs apparently follow similar trends. Although very little research is done in Canada, international firms apparently adopt accounting practices which result in charging both parents and subsidiaries for some portion of total research costs. The extent to which the methods chosen are appropriate is another question, but some such allocation arguably makes international cost comparisons more valid than they would be in the complete absence of any allocation. The very much larger outlays for sales promotion also apparently follow the same pattern. For example, the Report of the Kefauver subcommittee showed that 22 of the largest drug firms doing business in the United States in 1958 (both domestic and foreign-based) reported that 24.8 cents in each sales dollar was devoted to selling activities. (5a). The PMAC submission shows that 30.0 cents in the sales dollar of 41 of its members was devoted in 1964 to selling activities. (6b). It is with regard to the international impact of selling activities, however, that the influence of the United States industry on the Canadian industry is most direct. American drug firms promote brand names, not generic names. So do their Canadian affiliates. United States medical

journal advertising is intense; since there are many more U.S. medical journals than there are Canadian, many American journals are read in Canada, and the Canadian physician is correspondingly exposed to the advertising message on behalf of brand name products made and promoted in the United States, with predictable implications for prescribing practices. (2b.) Also, non-professional magazines may convey brand names to the public.

4. In both countries, the institutional structure of the markets in which drugs are sold to patients are broadly similar. Brand name advertising and other sales promotion tactics induce the physician to write the great majority of prescriptions by brand name, and these prescriptions are largely dispensed by retail pharmacies. A substantial minority of drug purchases, however, are made by hospitals, by public agencies, and by other buyers with more bargaining power than the captive patient. Most importantly, in neither country is there any system of comprehensive national health insurance which provides for, or influences the cost of, prescription drugs, since the presence of such a system would greatly complicate any international comparisons.

B. Differences:

1. In the United States, retail pharmacists add a 66 2/3% mark-up over invoice cost, in order to arrive at prescription charges. In Canada, a dispensing fee may be added to the 66 2/3% mark-up, or a "professional fee" may be added to invoice cost. There is also an eleven per cent federal sales tax at the manufacturer's level, from which purchases by hospitals and other public agencies are exempt.

2. There are differences in applicable tariff rates, and in Canada special "anti-dumping" duties may be imposed under certain circumstances.

3. In the United States, patents may be obtained on drug products as well as drug processes, and there are no statutory provisions in the Patent Act for compulsory licensing of drugs, even if the patent is abused. In Canada the laws as written give the consumer more protection. Drug products produced by chemical processes cannot be patented as such, only

in conjunction with a patent on the process by which they are produced. Furthermore, not only does the patent law specifically provide for compulsory licensing in case of the abuse of a patent, but this remedy is also available for drugs generally unless in a particular case the Patent Commissioner sees good reason not to grant the license.

4. The Canadian Trade Mark Act contains a provision whereby a Canadian affiliate of a foreign company can prevent the importation into Canada of products purchased in the foreign country even though they bear a trademark identical with that of the Canadian affiliate, provided that the Canadian affiliate owns the particular trademark. This eliminates the possibility of legally importing many brand name drugs which may be selling at lower prices outside Canada.

5. The Food and Drug Directorate in Canada and the Food and Drug Administration in the United States have broadly similar powers and responsibilities. It appears, however, that the requirement that all prospective marketers of a "new drug" provide the same type of experimental and clinical testing evidence does impose unnecessary burdens on subsequent suppliers of compounds identical with those previously cleared for marketing by earlier applicants.

6. Resale Price Manintenance has been outlawed in Canada but is still in effect in most states in the United States.

One last prefatory comment is in order. In my presentation I may appear to be critical of the relative inefficiency of resource allocation which results from allowing the pharmaceuticals industry the same exemption from special economic regulation which is routinely accorded to all those industries which naturally tend to function competitively in a free market environment. But if the drug industry is left to itself, it will inevitably display elements of both monopoly and rivalry. Spokesmen for the industry continually refer to the extreme degree of competition among firms. Unfortunately, the "competition" referred to is of the cost-raising type rather than the price-reducing type. This might more properly be referred to as "rivalry" rather than "competition," since the latter term has the connotation, not only in economic theory, but also in general usage, of <u>price</u> competition.

In this regard I wish to make it clear that, as an economist, I have the highest regard for freely competitive private enterprise markets and the efficiency with which they allocate resources. Indeed, last year, together with several other academic economists, I was characterized by Fortune magazine as a "professional guardian of free enterprise." (8) However, my admiration for efficiently functioning free markets makes me all the more sensitive to the drawbacks of markets which do not possess those characteristics requisite to enable the unrestricted operations of demand and supply to produce efficient results. I regard the great majority of product markets in both Canada and the United States as being more or less workably competitive, but the market characteristics of the pharmaceuticals industry are such as to make it virtually a foreign body in an otherwise workably competitive economy.

In which respects does the drug industry depart from workable competition? A brief summary must suffice at this point.

(1) Essential to the effective operation of a free market is the ability of the buyer to choose among suppliers on the basis of an adequate knowledge of the price and quality of the alternative products which they may provide him. But in ethical drugs, the buyer has no practicable means of gaining access to knowledge of the range of price and quality alternatives in the market; indeed, his purchasing agent, the prescribing physician, is constantly over supplied with biassed information and misinformation which facilitates confusion and ignorance of prices.

(2) The price-conscious buyer should be able to identify the lowest-priced seller and purchase from him without artificial impediments. Instead, the possessor of a newly-written prescription is unable to buy any but the specified drug, regardless of price. The willingness of the price-conscious physician to prescribe lower-priced drugs may be compromised if he has been exposed to repeated attempts to disparage low priced drugs on the part of representatives of brand name drugs who contend that low price means low quality. And even if

a generic prescription is written, the buyer has no power to compel the dispenser to sell him a reasonably priced generic drug instead of substituting a less reasonably priced brand name equivalent.

(3) There must be freedom of entry into the industry by new firms, such that high profits being made by existing firms will attract new competitors who will, by engaging in price competition, drive profits down to competitive levels. But freedom of entry in drugs is greatly lessened by the existence of the patent privilege, the trademark device, and the necessity for newcomers to match the enormous advertising outlays of existing rivals.

(4) There should be an adequately large number of competitive sellers offering buyers genuine alternatives in terms of product price and quality; none of the sellers should be so large that he overshadows the magnitude of his competitors and poses a potential threat should they incur his displeasure. In drugs, restricted entry limits the number of sellers, and while there are few if any genuine product monopolies, the size of the major firms is certainly appreciably greater than that of their smaller generic-name competitors.

(5) A market is not workably competitive unless all firms act independently--there must be no overt or tacit collusion, no passive acquiescence in prior decision arrived at by others and established by mutual consent. While the Restrictive Trade Practices Commission Report did not charge the drug industry in Canada with any illegal overt collusion, there are two circumstances which act to hamper independence of action. First, there is the practice of price leadership and the pricing of new medications at exactly the same levels charged for existing substitute drugs. Second, there is the fertile field of patents. While an individual patent confers a monopoly, the scope of the monopoly privilege is limited. But in an industry with complex technology, the efficient production of a drug may require the use of processes controlled by rival patent-holders.

> The negotiation of the resulting cross-licensing agreements requires the mutual compromise of patent monopoly positions, and may well stimulate such meetings of the minds as will lead to the development of a greater sense of community of interest in policies regarding prices, production, and participation in world markets.

There is another respect in which the implications of the usual free market arguments need to be examined in the light of the nature of demand in the prescription drugs market. In a purely competitive market, buyers are protected in that they need pay no more than the competitively determined supply price for any product. But it deserves equal emphasis that they must pay no less than this price. Resources are not efficiently allocated unless the buyer is obliged to pay the full cost of the goods he demands, since in demanding them he is requiring the economy to employ scarce resources to produce to suit his desires, when these resources might be used equally efficiently in other pursuits. The true cost of employing a given level of resources in producing a certain product is the value of the alternative output which is lost by necessarily foregoing the employment of the same resources in producing another product. But this argument is most directly relevant only where the nature of demand is such that the desire for the good is voluntary; that the buyer should be willing to bid for a particular good or service in accordance with the positive benefit or satisfaction which he derives from its purchase. If demand is not voluntary, however, then the consumer cannot in the same sense be held liable for payment of the full cost of services rendered to him, since he did not voluntarily require that the economy devote scarce resources to serving him which could be provided only at the cost of sacrificing the output of other goods which these resources might have produced. This is not to say that the drug buyer should not, after all, bear the full cost of the drugs which he requires, since he is perhaps deriving benefit from them in the sense of avoiding prolonged suffering rather than enjoying positive satisfactions. Still, there is a difference between paying the full cost of financing an activity deliberately engaged in, as compared with one forced by accident

or misfortune upon the buyer through no real fault of his own. Considerations such as this do not necessarily justify assumption by the state of all responsibility for medical care--far from it. But a rational awareness of the risks and uncertainties of health care might, for example, induce a prudent man of sufficient means to participate in a voluntary health insurance program. The requisite means, however, will depend not upon the "full competitive cost" of drug supply, but upon the actual prices charged under far from purely competitive market conditions. Unless drug prices are reasonable, the possible full costs of drug therapy under a comprehensive health insurance program may be so great that excessively high premiums would be required, and the costs of drug therapy would not constitute an insurable risk for practical purposes. These are considerations which should be kept in mind when assessing the effects of the great variety of drug industry activities and expenditures on the cost of drugs, when such costs are borne in their entirety by individuals involuntarily afflicted and whose earning power and ability to pay may be seriously affected by the very condition which makes medication necessary.

In the absence of consumer knowledge of the market, and of workable competition among sellers, the firms are subject to only two limitations in their ability to exploit the drug buyer: self-restraint and public constraint.

Self-restraint is a sentiment essentially foreign to the efficient operation of a commercial enterprise; indeed, in a sharply competitive market, excessive self-restraint would lead to the demise of the firm. In drugs, self-restraint has probably seldom been a barrier to high prices and profits. Upjohn made over 30 per cent on its net worth after taxes in each of the deep depression years 1930-1935 in the United States. (4a) Still, self-restraint may have been more prevalent during the years before the second world war. But in the post-war era it became increasingly apparent to investors that the profit possibilities were simply too great not to be fully exploited. While it is very difficult for small firms to enter the drug market, it is possible for larger firms to merge with existing pharmaceutical firms, and for bulk

chemical and fine chemicals producers to integrate forward to the drug making and selling level. This was characteristic of the first postwar decade in the United States. As was amply documented in the Kefauver hearings, the change in the composition of the industry intensified the emphasis on sales promotion. The quantity of promotional matter increased sharply, and there were many physicians and medical educators who testified that the decline in its quality was no less marked. Many argued that Gresham's law was applicable to the new rivalry in selling efforts: that bad advertising drove out good. Some argued that the industry should be saved from itself: that it was necessary only for one or two less-than-scrupulous firms to deluge the physicians with advertising appeals of inferior quality, and all the rest had to follow suit. The offending firms were never specifically singled out. Still, the great majority of the unfavorable references were confined to a handful of firms. At any rate, the intensified rivalry which characterized the North American drug market in the 1950's probably removed the factor of industry self-restraint from the realm of possible solutions to drug policy problems.

Public constraint has offered the drug consumer only an inadequate safeguard. In the United States, drug administration laws have been passed only in times of acute crisis when public sentiment is temporarily aroused. Between crises, the government's attitude seems to be as permissive and uncritical as that of the general public, whose sentiments consist largely in the belief that "miracle drugs" are made by full-time miracle workers who can do no wrong. But miracle drugs can produce "miracle diseases." Dr. Walter Modell of the Cornell University Medical School commented that some 40-odd new diseases had been identified as brought about by the untoward effects of drug therapy. (9a). And a pharmaceutical atrocity like thalidomide can produce a whole "miracle generation." While crises like these spur action, interest soon wanes thereafter. But the drug interests are always alert to possibilities for minimizing the impact of control legislation.

In both Canada and the United States, food and drug legislation has been directed--and rightly so--at insuring the safety and quality of drugs. But too little attention has been directed to the problems of insuring the economic health of drug consumers. An adequate and comprehensive program of public constraint must include measures designed to keep drug prices at competitive levels and thus prevent the exploitation of the drug buyer. The problem at present is to determine which measures would be most appropriate.

CHAPTER II

THE DETERMINANTS OF DRUG COSTS AND PRICES IN THE CANADIAN MARKET -- AN ECONOMIC INTERPRETATION

Since the Committee is given the responsibility of making a study of drug costs and prices, major emphasis will be placed upon an analysis of the determinants of drug prices and costs; the relationship (if any) between the two under present circumstances, and the sort of relationship which might prevail under altered circumstances. As an economist specializing in the study of industrial organization and the public regulation of industry, my perspective is more general and more oriented toward the public interest than to the special interests which are the appropriate concern of spokesmen for drug firms and trade associations. Nevertheless, my orientation is first and foremost to economic realities, the most important of which is the profit motive.

A systematic analysis of drug prices and production must proceed in terms of an investigation of factors influencing supply and demand. Broadly speaking, supply is influenced by the costs of production, promotion, and distribution; by the channels of distribution; by the arrangements in terms of which production costs are allowed to influence pricing and production; and by the laws affecting the cost and availability of imports, the techniques of promotion, the difficulty or ease of entry into the market by new drugs and new firms, the taxation of drugs, and the ability of sellers to temper competitive pressures. Demand is influenced by the acuteness of the buyer's need for the product, his ability to pay (individually or through access to welfare case status), and the extent to which sales promotion efforts have the power to influence the physician and thus control the demand for a given drug.

The remainder of this chapter accordingly will be devoted to a discussion of the determinants of drug supply, drug demand, and drug price levels. The analysis will be organized under the following headings:

A. Factors Influencing the Supply of Prescription Drugs
    1. Costs incurred by manufacturers
    2. Costs incurred by distributors

B. Factors Influencing the Demand for Prescription Drugs

C. Market Price as Resulting from the Interaction of Supply and Demand

A. Factors Influencing Supply of Prescription Drugs

1. Costs Incurred by Manufacturers.

The costs incurred by drug manufacturers may be broken down into several broad categories:

(1) basic or fundamental research;

(2) applied research;

(3) product development;

(4) manufacturing the active ingredient;

(5) preparation of finished dosage forms;

(6) sales promotion activities.

Each cost category will be discussed and costs actually incurred and the activities undertaken under each heading will be contrasted to the scope of activities and level of costs appropriate to an efficiently competitive drug industry.

a. Basic Research

Basic research is an activity which inherently involves a distribution of benefits such that all of the advantages may not be captured by the agency incurring the costs. In economic theory, situations in which there are inequalities between private and social costs and benefits are referred to as "externalities" in that the private agency responsible for a particular activity need not be held internally accountable for all of the costs incident to the activity; nor may it reap internally all of the benefits. The most prominent examples currently discussed are "external diseconomies" resulting from waste disposal by means which may minimize private cost to the disposing firm, but which impose social costs upon the economy at large through the avenues of air pollution, water pollution, etc. Basic research provides a good example of an "external economy" in the sense that the agency undertaking the research may incur all of the costs of the operation, which then become private or internal costs to the firm, but the usually far-reaching benefits of successful basic research projects can seldom be captured in their entirety by the agency doing the research. Some of the benefits may be realized by competitors in the same industry, some by the

developers of new products and new applications in other industries, and some may be realized by the economy at large. Hence, basic research is the sort of activity which is not ideally adapted to the type of cost-vs.-revenue calculations which a private firm must make. A drug firm which engages in truly fundamental research must ask itself the following questions:

(1) What is the risk of failure of a given project?

(2) If the project is successful, will the findings ever be commercially applicable?

(3) Will the resulting findings ever lead to patentable discoveries?

(4) Will the time horizon between initiating the research project and its fruition in the sales of commercially marketable products be sufficiently short that the discounted rate of return on the investment will justify the outlays?

(5) Will the "gestation period" of product development for patentable discoveries be short enough that patent protection will be commercially profitable?

(6) Will the discoveries prove to be of equal or greater benefit to the rivals of the firm?

(7) Will the discoveries prove to be of greater application in industries outside the pharmaceuticals field?

(8) Will the discoveries pose the threat of obsolescence to presently profitable products?

Fundamental research is always a highly risky activity--for each success there are a multitude of failures; this is the nature of basic research. Furthermore, the sort of information resulting is often not patentable in the form in which it is obtained, and the "gestation period" between path-breaking basic research and the embodiment of the results in successful innovations is typically of considerable, but unpredictable length. The combination of high risk and long gestation period is in itself enough to discourage the typical firm from undertaking very much basic research. This is particularly true in an industry like drugs, where the rate of return which can be made by investing funds in applied research, product development, and sale promotion is very high. If the firm can make in the range of 15 per cent per year on funds invested in relatively shorter-run activities like the

above, the expected returns from fundamental research activities must be extremely high in order to make them seem worthwhile after discounting these expected returns at the firm's internal opportunity cost of funds of 15 per cent for a period of perhaps ten years or more prior to any payoff. When to this is added the risks that rivals in the industry, or firms in other industries, or the society generally, may stand to reap the major rewards of basic research, it is understandable that drug firms do as little truly fundamental research as they appear to undertake. (5b) Indeed, this is true of private industry generally. It must be admitted that problems of measurement are difficult. It is difficult to define basic research and to separate it from applied research meaningfully. No statistics are available which distinguish between basic and applied research carried out by private and public agencies in North America. The only estimates known to me which cover all industries and distinguish between basic and other types of research are those made by David Novick of the RAND Corporation for industry expenditures (both publicly and privately financed) on research and development in the United States in 1959. (4b) Dividing his analysis of these activities into four stages on the basis of an increasing degree of certainty of payoff, and a decreasing potential for long-range social benefits, Novick allocated an estimated total expenditure of ten billion dollars as follows: Basic Research, one per cent; Applied Research, three per cent; product development (development, testing, evaluation, pilot plant production), 26 per cent; Product Application (application research, applied testing, applied evaluation), 70 per cent. Most research is concentrated in a few industries (aircraft, electronics, chemicals) and much of this is financed by the federal government. When one takes into account the amount of basic research done in universities and by foundations, it is very likely that the great majority of basic research is undertaken and/or financed outside the sphere of private industry, as is economically only reasonable.

In order to embark on a given long-term basic research program

which because of its nature is believed to be of possible benefit only to the pharmaceuticals industry, a drug firm would have a greater degree of assurance of the commercial value of the program in proportion as its market position approaches long-run, unconditional monopoly of the entire industry. If the basic research is also expected to have application to the chemicals industry generally, then the firm might be reluctant to invest an adequate amount of resources to the extent that its market position falls short of long run monopoly control of the chemical and pharmaceuticals industries. If, however, significant benefits are likely to accrue to a number of other industries and to society generally, the "external economies" become so important that only an agency specifically endowed to undertake basic research (whether philanthropically endowed or financed by society generally) can be expected to assume the costs of a comprehensive program on the assumption that the benefits accruing to those who finance the agency will be commensurate with the costs.

Regarded from a slightly different perspective, basic research is simply not a very dependably profitable investment from the standpoint of a firm allocating its funds between different activities on the basis of expected net rate of return over time. At any given point in time, a profitable firm will always have many competing uses for funds which offer higher average expected net returns than fundamental research. This certainly does not mean that profitable drug firms will completely shun fundamental research, but this consideration implies that they will, for perfectly logical business reasons, allocate only a fraction of the funds to basic research which the long-run social and economic importance of the activity justifies. It is no exaggeration to say that fundamental research is ultimately a philanthropic activity, in that it always has a potential for benefitting society generally. Hence privately endowed universities and foundations as well as publicly financed agencies may most appropriately be expected to undertake the greater part of a nation's truly fundamental research effort. Indeed, the public is largely

responsible for the magnitude of the basic research effort in a nation. From the public comes not only the few philanthropists who endow universities and research foundations, but also the initiative to authorize publicly financed research programs and facilities, and to permit subsidization of private research through such devices as the recent 150% tax writeoff for increases in certain types of research investment in Canada. The PMAC Submission indicates agreement with this position:

> "Appropriately enough, basic research is carried out in the universities, while applied research is the province of industry."

(6c). The implication is clear, however, that since basic research is not the province of industry, the cost of drugs is not a reflection of any great expenditure by firms on fundamental research. And of course it is fundamental research which in the long run is socially the most productive form of research.[1]

Under efficiently competitive conditions, therefore, private drug firms would not be expected to devote any significant share of available resources to basic research, since it would not prove sufficiently profitable to the individual firm. The industry would instead be dependent upon publicly available results of basic research done by more broadly-financed organizations. And from all appearances, the amount of fundamental research undertaken by North American drug firms does not bulk very large in relation to total revenues. But this does not mean that private drug firm activities give rise to no distortion in the spectrum of basic research efforts. It may be the case that too little basic research in areas relating to health and therapy is done by non-industry sources, in part because the ability of the industry to pay high salaries due to the high profitability of drugs under present market conditions results in drawing too large a part of the very small

---

1. In its recent presentation to this Committee, representatives of one major pharmaceuticals company claimed that their firm had undertaken truly fundamental research in Switzerland over a period of five years without any tangible results as yet forthcoming. If this is the case, this company might well be commended for its persistence in what at present appears to be a truly philanthropic gesture in the interest of fundamental research. This commendation would have to be qualified, however, in that as part of the company's budget, this research has been paid for entirely by purchasers of medications, who are probably not in an ideal position to afford subsidy of basic research which may benefit the entire world. This is one major criticism of drug industry research generally.

pool of qualified investigators and technicians away from public employment in basic research and toward private employment in applied research, product development, and product application. (The major drawback, perhaps, of the fact that Canadian drug firms do little research in Canada is not that the quality of available drugs suffers, but that Canada loses many of its highly trained research workers because of lack of opportunities for domestic employment.) In order to rectify the situation, it may be desirable not so much to attempt to increase the amount of basic research done by private firms, as to take steps to reduce the ability of these firms to drain off very scarce human resources for employment in less productive capacities than they might be assuming.

b. Applied Research.

Applied research takes a variety of forms in the drug industry. Basically, however, drugs are a branch of the chemicals industry, and in chemicals, applied research is rationally viewed as a means of implementing a profitable marketing operation. Applied research is risky, but less so than fundamental research. It may be productive, but again the total potential is less than in the case of basic research. There is less likelihood that the benefits of successful programs will accrue to parties other than those undertaking the applied research, although this possibility cannot be ignored. But on balance, applied research is likely to be less slighted than basic research by private firms. (This is not to say that applied drug research by public or non-profit organizations is necessarily totally inappropriate, but since such bodies as universities are naturally best adapted to basic research, it may be desirable to institute particular types of non-profit projects if it is considered appropriate to supplement the applied research efforts of private drug firms. And public patent policy becomes a more important issue when applied research is undertaken. Should public discoveries be unpatented, or, if patented, be freely licensed without royalties?)

What sort of applied research expenditures would be incurred by drug firms operating in an efficiently competitive market? To the extent that competition drives prices down closer to the level of production costs, it might be suggested that this would seriously limit such efforts on the part of firms. Reserving judgment for the moment in regard to the possible desirability of limiting applied research efforts, let it be instead pointed out that the share of total research and development outlays in the sales dollar of the Canadian drug firm is not as great as the industry would like to have us believe. According to the PMAC Submission to this Committee, the ratio is around 7 per cent. (6d). Novick estimated that about three per cent of research and development expenditures are devoted to applied research; the ratio is no doubt greater in drugs, but even if we assume that it is about ten times as great, the cost of applied research is still only about 2 per cent of the sales dollar. But we cannot proceed to speculate on the appropriate level of applied research outlays in an efficiently competitive drug industry without specifying what changes have been assumed in order to produce efficient competition. It is not profitable to discuss in detail the conjectural effects of possible changes in market structure, but it is essential to observe that competitive performance will not be obtained without a reduction in the power of a patent holder to limit entry into a particular drug market. To the extent that this power to limit entry is being reduced in Canada in at least some drug markets, the stage of efficient competition is being approached.

In an effectively competitive drug market, the character rather than the level of applied research is more likely to be altered. The direction and emphasis of research is clearly influenced by the nature of the patent system, by the impact of the patent system upon the organization of the industry, and by the effect of the activities of the industry on research outside the industry. In fact, the direction of research is no doubt greatly altered by the mere existence of the patent privilege for drugs. The prospect of patent monopoly stimulates research

efforts in the direction of patentable discoveries and inventions, and in so doing correspondingly acts to reduce the proportion of research in areas where no patents can be obtained. This discriminates at the outset in favor of applied research and against basic research. It also discriminates among different avenues of applied research. It clearly results in the placing of an unduly intense emphasis on chemotherapy. While chemotherapy will long be a fruitful area for research, it is inescapable that the complementary fields of nutrition, public health, biochemistry, and preventive medicine have been relatively underinvestigated. Antibiotics provide the most obvious illustration. Fear has been expressed that antibiotic therapy may eventually prove to be a blind alley because of overuse and the development of resistant strains of micro-organisms. A case could easily be made that too much effort has been expended in activities which tend to make micro-organisms increasingly resistant to control, and too little has been done to attempt to make man naturally more resistant to micro-organisms.

Any patent system, by biassing efforts toward applied research, will reduce the amount of basic research findings which can be applied, and ultimately depress the productivity of applied research. Much has been made in recent years of the "increasing cost" of drug research for new discoveries. But to speak of increasing costs is just an indirect way of referring to decreasing productivity of efforts. The nature of the patent system--its application to products and/or processes--will further influence the direction of applied research. A patent law which protects new products, either directly or through process patents, will bias applied research in the direction of devising new products rather than investigating the properties of old ones. As the archetype of applied research in drugs, let us take the methods by which new drugs are discovered or contrived. As Professor George Wright has explained in his Submission to this Committee, the molecular engineering approach is favored over the multiple screening method because new compounds are generally patentable, while the discovery of new uses for older compounds is not. (7b).

To the extent that patent reform reduces biases of these types, fewer impediments to the efficient allocation of resources by drug firms to applied research will exist. In an effectively competitive drug industry, there will be a greater variety of fundamental research findings on the basis of which applied research can be conducted. The potential improvements in nutrition, public health and preventive medicine from research efforts will become more readily capable of attainment. The bias in favor of devising new compounds instead of evaluating the properties of existing compounds will be reduced. Whether the total level of expenditures on applied research would be reduced or increased in an effectively competitive drug industry is a matter of uncertainty, but the expenditures would be more productively invested.

Let us contrast this with an appraisal of current practice. The major contributions of North American drug firms in the postwar period have been in the field of applied research--the discovery and development of the so-called "broad spectrum" antibiotics. For these drugs, no truly fundamental research was involved. The basic discovery had been made in England in 1928, the problems of large-scale production had been solved by government scientists during the second world war, and it was common knowledge that many moulds occured in nature, some of which might be capable of yielding new antibiotics. All that remained to be done was to collect and analyze soil samples, a rather tedious trial-and-error process of a routine but exacting nature, which the technicians involved could hardly have found intrinsically very stimulating. But since no new fundamental research was involved, the returns to more and more intensive exploitation of the same basic method have continually declined, very sharply since the mid-1950's, as is admitted by industry analysts.

But not all of the antibiotics marketed were of equal quality, nor did they represent comparable inputs of research effort. The drug patent, by providing the prospect for at least a limited period of monopoly

control of a given substance which could be assigned an abstract brand name and then advertised as a unique entity, inflated the amount of applied research done, and redirected it toward the overly intensive exploitation of approaches known in the past to have produced profitable drugs. Since the number of such known approaches is limited, it is within the capacities of major firms to explore several of them, and since this is known by all firms, the research programs of the large firms tend to duplicate, at least in part, the programs of their major rivals. This is evident not only from the testimony of doctors during the Kefauver hearings, but is also witnessed by the near-simultaneous discovery of several major drugs by two or more firms. This represents a compounded misallocation of resources; not only are scarce talents diverted from basic to applied research, but wasteful duplication of effort appears to be the rule rather than the exception. (A certain amount of duplication of effort may be desirable, but not on the scale encountered in drugs.) These disadvantages of patent-induced research are further compounded when the proven profitability of marketing patented drugs leads firms to engage in the increasingly well-known game of molecular manipulation, with the object of devising a patentable deviant of an existing patented drug, which can serve as the vehicle of an intensive sales promotion campaign in the hope of profit.

Hopefully the new manipulated drug will be at least in some regards superior to the drug which it is intended to supplant, but the essential purpose is to get another product on the market which can be promoted in rivalry with its substitutes, regardless of the actual comparative therapeutic merits of the drug. During the Kefauver hearings, two physicians who had served as medical directors for major North American drug firms testified to the extent to which therapeutic considerations were subordinated to profit possibilities. Dr. A. Dale Console, former medical director for Squibb, upon being asked whether there was much drug research which produces nothing worthwhile and is not intended to, responded:

> "I think the majority of it is in that category...and I should point out that with many of these products, it is clear while they are on the drawing board that they promise no utility; they promise sales. It is not a question of pursuing them because something may come of it. It is quite clear there is no point in pursuing this: that you won't end up with a product that has any real value; but it is pursued simply because there is profit in it."

(4c). Dr. Console also noted that imitative research could crowd out legitimate work.

> "When a 'crash program' comes along in which some product is being pushed in order to get it out before a competitor gets it out, it is not unusual for a worthwhile research program to be postponed so that the people can be taken off it to be put on the 'crash program.' Very frequently some of these programs are never picked up again. So that I think that good research is actually hampered by this type of thing."

(4c).

Dr. Haskell J. Weinstein, former medical director of the J. B. Roerig division of Pfizer, indicted the industry for wasting the time of their research staffs:

> "Their talents should not be expended on patent-bypassing chemical manipulations, on ridiculous mixtures of drugs, or inconsequential additives to established drugs. Since the number of well-trained capable scientists is severely limited, their potential should not be wasted. The long-term benefits of the appropriate utilization of the abilities of these skilled individuals would be immeasurably greater."

(4d). Hence patents have not only induced a distortion between basic and applied research, but in making the latter budgets relatively too large, have induced wasteful duplication of effort and the misdirection of effort toward rivalry-oriented molecular manipulation, the development of often irrational combinations of existing drugs which lack flexibility and compound the problems of dosage and toxicity, and the devising of additives which represent often questionable and perhaps unnecessary flourishes in the direction of increasing the absorption rate of a drug, guarding against side effects, and the like.

As a concluding example of molecular manipulation and the "battle of the additives," let us take the drugs related to erythromycin, discovered in 1952 by Lilly. Dr. Harry F. Dowling of the University of Illinois Medical School explained the ensuing exercise in product development

rivalry to the Kefauver Subcommittee. (4e). Pfizer in 1953 concocted a closely related analog, carbomycin, which affected the same bacteria as erythromycin, but proved less effective in human disease than in the test tube, and was finally withdrawn from the market in 1960. In 1956, Pfizer introduced another closely related analog of erythromycin, oleandomycin; and in 1957, a modification of oleandomycin, triacetyloleandomycin, which was highly advertised as a major breakthrough in that the same oral dose as oleandomycin brought somewhat higher concentrations of the drug in the bloodstream. Lilly countered this in 1958 by modifying its original erythromycin to market it in the form of its propronyl salt, which was claimed to produce a higher concentration of the drug in the blood than triacetyloleandomycin. Resources were therefore spent in producing five drugs to serve the purpose of one, since slightly higher doses of erythromycin would have been as effective as the later derivatives.

c. Product Development

In this category a great many activities are included. The development of new products requires experimental testing to determine pharmacological activity and toxicity in laboratory animals, the determination of appropriate dosage forms, the conducting of initial clinical trials, the obtaining of permission from the Food and Drug Directorate of the Department of National Health and Welfare to market the new drug, the construction of pilot plant facilities, and related activities. Also included in development would be subsequent product application work in connection with long-run evaluation of the total effects of the drug, possible improvements in dosage forms, revisions of brochures, and the like.

In an efficiently competitive drug industry, profit prospects from marketing new drugs would be modest, and extreme haste in development would not be a great temptation. Development activities could proceed at a pace appropriate to the importance of careful drug evaluation. To eliminate or minimize the effects of proprietary bias in

evaluation, it would be desirable to have clinical testing carried out under other auspices than those of the discovering firm. Minimization of bias would result from having evaluation undertaken by public or other bodies outside the industry. But it would probably not be practicable to require that educational or government agencies perform clinical evaluation of all drugs, even though the total number of drugs evaluated would no doubt be smaller in an effectively competitive industry because of decreased motivation to produce drug copies and minor modifications. Preferable arrangements might be some variant of an evaluation program financed jointly by the entire drug industry. There should be no premium on haste, since each step in development is time-consuming if properly carried out. And the consequences of improperly evaluated drugs are not pleasant to contemplate. Dr. C. D. Leake of Ohio State University has trenchantly noted,

> "There is no shortcut from chemical laboratory to clinic, except one that passes too close to the morgue." (4f).

Under present arrangements, however, a great premium is placed on speed in rushing a new drug through the development phase and into commercial marketing. In order to secure permission from the Food and Drug Directorate, it is necessary to submit a sufficient amount of experimental and clinical data to establish the presumption that the drug is reasonably free from hazards of acute toxicity, and is a reasonably expedient agent in combatting those disorders in which it is claimed to be effective. But it takes time to conduct sufficient experiments and to carry out enough clinical studies to estimate probable toxicity in general use. In the United States, many instances of inadequate experimental work were unearthed by the Kefauver Subcommittee, although it is probable that conditions have improved since the thalidomide-inspired passage of the Drug Amendments Act of 1962. (And, as Dr. Alan Davidson has observed in his submission to this Committee, although no new Canadian legislation resulted, Canada was an indirect beneficiary of the new regulations in the United States). It also takes time to have new drug submissions studied and processed. In drug marketing,

many firms are often working on the same or related products at the same time, and each desires to cut the period between discovering and marketing to an absolute minimum, since the order of priority in market appearance usually determines the relative sales ranking for different brands of the same types of drug. Consequently, the motivation is to limit experimental and clinical work to the minimum acceptable level, to skip stages in product development, such as the pilot-plant stage, and to apply pressure to the staffs of regulatory agencies in such a way as to facilitate rapid approval. For example, Duncan of Lederle disclosed that his firm took the risk--which could have been costly and wasteful--of by-passing the pilot-plant stage in the development of triamcinolone. (13). And disclosures by former Food and Drug Administration employees during the Kefauver hearings gave evidence of the deplorable pressures which drug firms exerted on regulatory personnel, and the disgraceful condoning of such pressures by officials of the agency. (4g).

Another of the symptoms of excessive pressures for rapidly testing an excessive number of new drugs is that the time of the best available researchers is soon completely filled, and less capable, less experienced, less discriminating, and perhaps even less scrupulous individuals must be relied upon to conduct these tests. (While I understand that abuses in Canada have never been as severe as in the United States, similar pressures are likely to exist.)[1] Dr. Maxwell Finland of the Harvard University Medical School produced a very enlightening example at the Kefauver hearings. He cited an instance

---

1 Dr. C. Gendron, Medical Director of Cyanamid of Canada, mentioned before this Committee that there were only about 75 available qualified clinical investigators in Canada (7ii), far too few to meet the demands for their services. And yet the scarce time of these men may be wasted if they are induced to participate in drug studies designed to promote drugs rather than investigate them. To quote from the Government of Alberta Brief before the Restrictive Trade Practices Commission in 1961:

> "In Alberta, as a result of past experiences, where precipitate promotion interfered with objective clinical evaluation of new products, most clinical consultants refuse to undertake evaluation unless a clear understanding is made that no promotion of a product is contemplated until adequate investigation to allow valid conclusions is completed. In the past, it has happened that active promotion of a drug with its attendant ballyhoo has been initiated in the United States within a few weeks after an investigation has been started at the University Hospital in Edmonton at the suggestion of the drug firms. This inevitably results in the investigator becoming an unwitting party to the promotion." (1j)

where reports by a clinical investigator claimed the successful treatment of 100 cases of staphylococcal pneumonia by a particular drug, without a single mortality. Since the subjects were infants and children, and since under even the best of circumstances, the mortality rate is 50% in children under two years of age, the drug would appear to be a godsend. But upon scrutiny of the cases, Dr. Finland was satisfied that not a single case of staphylococcal pneumonia had been present, and inferred that the investigator had been unable to diagnose the presence or absence of the true disease from the laboratory cultures with which he was supplied. Dr. Finland concluded ominously:

> "This is the sort of thing that I say is dangerous because another doctor who knows how to make a diagnosis of staphylococcal pneumonia will use that drug to the peril of his patient."

(4h). Incompetent individuals should not be expected to conduct such studies; one great advantage of reducing the number of drugs to be evaluated would be a concomitant increase in the average quality of evaluation. Another advantage, less dramatic but in the long run very important, is that by reducing the claims on the time of medical educators, a decrease in the number of drugs to be evaluated would alleviate the competition between teaching and drug research for the time of the medical school faculty member, and increase the quality of medical education.

While the transformation of the drug industry to a more competitive state would tend to lower costs of most functions, it would probably tend to increase the cost per drug of product development by enabling more thorough and responsible evaluation. Total product development costs might not increase, however, since the number of drugs developed might decline as a result of eliminating motivation for producing minor modifications under great time pressure.

d. The Manufacturing of the Active Ingredient.

Precise information on the cost conditions under which the active ingredient in a typical drug is manufactured is not generally available. Such evidence as exists appears to confirm the economist's

natural suspicion that when many firms produce rival brands (or rival molecular versions) of the same compound or family of compounds, there may be excess capacity in that market demand is not great enough to keep the plants of all producers working at full capacity. And excess capacity imposes economic costs. For example, the Pharmaceutical Manufacturers' Association in the United States retained Dean E. V. Rostow of the Yale University Law School to defend the industry's drug price policy and patent privileges before the Kefauver Subcommittee. Rostow contended that although production costs for tetracycline represented only ten per cent of the price to the druggist, such a gross profit margin was not unexpected in view of the rapid increase in demand for the drug. The possibility of very high profits is very likely, contended Rostow,

> "if, as would seem natural, new entrants required some time to perfect their methods of production, so that there was some lag in capacity as compared with demand."

(9b). However it developed that Bristol, which was producing about a third of the total output of the drug, was then operating (1955) at only about twenty per cent of capacity. (9d.) Obviously, such enormous over-capacity increased the fixed costs per unit of production. In a competitive market, this would have forced price reductions in order to increase sales and reduce excess capacity. But tetracycline was produced under very elaborate patent licensing and cross-licensing arrangements, the genesis of which was attacked by the United States Federal Trade Commission, which in 1963 issued its verdict that the patent had been awarded to Pfizer only because of misrepresentation and the withholding of information from the patent examiner by Pfizer and Cyanamid. (14). Hence Bristol maintained its price level and tried to combat excess capacity by producing penicillin jointly with tetracycline. But Bristol did contemplate price reductions on penicillin in order to increase sales, since there was no effective patent control over penicillin. (9d).

In an efficiently competitive drug industry, each stage in the production process would be accomplished at minimum cost, and without

the burdens of persisting excess capacity. In drugs, the facilities required for the production of active ingredients apparently vary considerably. For those active ingredients which can most efficiently be produced by truly large-scale or mass-production methods, production by makers of fine chemicals or even of bulk chemicals would be appropriate. But for many drugs, the amount of investment required to produce the active ingredient, while perhaps large in absolute terms, is relatively modest in comparison to the amount of funds available in capital markets. Relatively small firms can efficiently produce the active ingredients in these cases. Mass production methods are not appropriate for many drugs since the physically minute quantities used in medications require only a small total annual volume of output. (4i). Even so, it may still be more efficient for a small firm to contract with a larger firm for the production of the basic drug. Under competitive market circumstances, relative economies of production versus preparation of dosage forms and distribution should control the functions assumed by different producers at different stages in the industry. If patents were no great barrier to entry into a drug market, raw materials and intermediates could be made by bulk chemical companies, the active ingredient could be produced by fine chemicals producers, and the finished dosage forms could be tabletted and bottled or otherwise prepared by drug makers to be distributed through various channels. Without barriers to entry, comparative costs of each process would determine the allocation of tasks among different firms. As far as financial requirements for drug making itself are concerned, there are no reasons why a large number of relatively small firms might not compete effectively in the market, a situation conducing to efficient price competition.

Under present circumstances, however, there are a number of market factors which distort the picture and introduce other criteria than comparative costs as determinants of the distribution of efforts at various stages of the industry. A relatively small drug maker may find a new drug, patent it, and then be induced to undertake the

production of the active ingredient himself, even though his comparative advantage does not lie in this area because of inexperience, inappropriate facilities and general lack of adaptation of his operation to the manufacturing of fine chemicals. Still, production may be undertaken--at higher cost levels than necessary--in order to prevent the "know how" which is not necessarily disclosed in the patent from being acquired by another firm. Where several firms are producing lots of suboptimal size at higher costs than would be incurred by a single manufacturing chemist supplying all of them from his own production, costs could obviously be reduced by recourse to more efficient practice. Under the circumstances induced by patents, these disadvantages can be overcome only partially by such means as forward integration, usually through merger, where manufacturers of bulk and fine chemicals operate or acquire pharmaceutical houses. Some of these mergers occurred before the era of "wonder drugs," such as Lederle's takeover by American Cyanamid in 1930; but most are of later date, as witness Olin-Mathiesson's absorption of Squibb, Dow Chemical's acquisition of Allied Laboratories and Pitman-Moore, Merck's merger with Sharp and Dohme, Pfizer's development of Roerig, and others. The Canadian scene is certainly no stranger to such mergers, with the acquisition of Ayerst by American Home Products, of Horner by Carter, and of Frosst by Merck being only the more prominent instances.

Patent restrictions are not the only factors stimulating forward integration by merger. The practice of intense sales promotion of drugs under brand names creates economies of large scale marketing at the drug firm level and creates a barrier to entry where production methods are such as to permit entry. The ability of small drug companies to compete with their former peers is reduced by such forward integration, and the power of the merged firms to resist or avoid competitive forces is enhanced. Also it has frequently been surmised that the decline in the standards of drug advertising and promotion had some relationship to the take-over of some previously conservative firms by companies not

specialized to drugs, but accustomed to applying only the sales yardstick when measuring the appropriateness of advertising appeals, such as producers of cosmetics, proprietaries, and "patent medicines."

Where the danger of loss of coveted "know-how" is not relevant, drug firms may contract out the production of active ingredients to producers of fine or bulk chemicals. It is then striking to note the relationship of the price of the bulk drug in comparison with the market value of the substance when embodied in medications and sold to distributors. Ratios in the vicinity of one hundred to one are not unknown.[1] The reason for this is simply that there is price competition between the firms which manufacture the active ingredient, but for patent and other reasons, there is none in the sale of the finished product. In a purely competitive industry this could not happen. With competition, the price of the finished drugs would decline to be more in line with production costs for the active ingredient.

It is difficult to generalize about the effects of present industry arrangements on the level of manufacturing costs for the active ingredients in view of the virtually complete absence of empirical evidence on costs and utilization of capacity. It is true, however, that investment in excess capacity means that earnings as a percentage of net worth are depressed below the levels which would obtain under optimal capacity-output relationships, such as would of necessity tend to prevail under price competition. Hence a moderate rate of return on investment may not indicate competition, but merely excess capacity. Similarly, if a firm argues that since profits amount to only about ten cents per dollar of sales, the complete elimination of profits would cut prices only ten per cent, it should be kept in mind that the costs occasioned by the existence of excess capacity also have their share in the sales dollar, and such costs could by and large be eliminated through

---

[1] Empire estimated that it could sell bulk diazepam at $170 per kilogram while the value of a kilogram of diazepam embodied in dosage forms is about $20,000.00, a ratio of about 125 to one (see pages 40 and 41 of this submission).

adopting reforms which, by compelling firms to operate more efficiently, required them to forego the luxury of excess capacity.

Evidence on the cost of active ingredients in bulk form to Canadian drug firms is partially obscured by the fact that about 80 per cent of such ingredients is imported, usually from foreign affiliates, and the prices set in inter-company transactions of this sort may not reflect the true cost of production of the substance. There are several reasons for this. First, the valuation is likely to include an unknown margin of profit to the foreign affiliate, over and above allocated full production costs, hence overstating the latter. Second, the effect of drug tariffs should partially offset this tendency, since a high valuation would mean, other things being equal, a high tariff liability. Regardless of the value for tariff purposes, however, the tariff should be distinguished from the level of production costs. Because of the low ratio of production cost to price, even tariffs of 20 to 25 per cent add only a very small amount relative to consumer price. Information given by the Minister of National Revenue to this Committee indicates that customs duty accounts for only 2.5 per cent of the consumer price for drugs imported in an unfinished condition for further manufacturing in Canada, or in bulk for full or partial packaging in Canada. For goods made predominantly from Canadian materials, with some imported materials and supplies, the ratio was .7 of one per cent. (7c). However, if competition reduces price levels, this ratio will correspondingly increase. Third, the effects of the dumping duty which may be imposed on certain drugs might be to make the foreign parent set a relatively high price on active ingredients exported in bulk form to Canadian subsidiaries, reasoning that if a lower price were set, revenues would be lost through dumping duties paid, while a higher price would merely increase the reported profits of the parent at the expense of the Canadian subsidiary. This is the view put forth in the Report of the Restrictive Trade Practices Commission (1a) and is obviously correct to the extent that valuations for dumping duty purposes are set in excess of manufacturing

cost plus a profit allowance reflecting the rate of return on the manufacturing operations *per se* experienced by the parent. But in an integrated operation it is very difficult to say what part of the company's overall profitability is due to the operation of various stages in its production process. Hence the precisely relevent value for dumping duty purposes cannot be determined in the absence of any independent market for the good in question. In practice it seems that where the dumping duty potentially applies, active ingredients in bulk form would usually be valued at manufacturing cost plus a 50 per cent markup. This is low in terms of the profits generally realized by the industry; the Minister of National Revenue cited a study showing that in the United States gross profits on drugs from 200 per cent to 1200 per cent are common. (7c). Under these circumstances it would appear that the application of the dumping duty is not likely to result, in itself, in any great inflation of parent company profit levels at the expense of those of Canadian subsidiaries. But if an increase in competition in the industry were to occur and gross profit margins were to decline, an examination of the dumping duty provisions might be in order. Specific reforms are discussed in Chapter III on this submission.

It may tentatively be concluded that the production cost of imported bulk drugs may be overestimated. The prices charged for such imports necessarily include a profit markup over cost which may be substantial. For those drugs subject to dumping duty, an additional motive exists to insure that customs valuations are high relative to costs. Hence in measuring the production cost of bulk drugs by reference to the price charged by exporters it must be realized that such prices may be substantially in excess of actual costs.

e. Preparation of Finished Dosage Forms.

The technology of the preparation of finished dosage forms, and the modest capital requirements of such operations, make this stage of the industry ideally suited for efficiently competitive market performance. The compounding of finished dosage forms typically involves

what are technologically routine and elementary processes for most dosage forms. For tablets, the tabletting and bottling of the preparation involves technically trivial operations, which are carried out at very low cost. For other dosage forms, such as injectables, processes may be more involved and costs appreciably higher. Still, for the typical pharmaceutical preparation total "factory costs" (making the bulk ingredient and producing the finished, packaged dosage forms) are a very small part of the wholesale price, and an even smaller part of the retail price. There is no reason why very small firms could not contract out the manufacture of the bulk powder and then tablet and package the finished dosage forms on the basis of a very modest total investment. Hence brisk competition between many small sellers of pharmaceutical products could develop if production costs were the only barrier to entry into the drug field. In most major industries, it is precisely this element of production cost--the technological economies of large scale, capital-intensive production--which provides the major barrier to entry, and hence preserves the market power of existing firms.

But if patents and sales promotion patterns were not present to prevent entry into drug making, pressures would develop to transform the drug market into a structure with a relatively large number of relatively small producers selling largely identical products and producing efficiently at low price levels consistent with low production costs and only competitively determined rates of return on investment.

While available evidence is largely fragmentary, it seems to indicate that the costs incurred by all firms for producing standard capsule forms and packaging them are very low relative to the prices charged by the brand-name firms, and that much of the price competition which does exist between brand-name and generic-name versions of the same drug comes about because for such drugs the absence of tight patent control over manufacture and/or sale of the bulk powder enables small firms either to produce or to obtain the bulk powder at the low prices which reflect only the competitive supply price of the bulk powder. The firms then tablet and package the drugs and sell them at low prices reflecting low costs of production. This is virtually the

only instance of vigorous price competition in the entire industry. It does, however, show the sort of pattern which might develop if barriers to entry were removed, and numerous small competitive firms were to enter the market for producing existing drugs.

In an efficiently competitive industry the relationship between production costs and market prices is close and direct. Indeed, the acid test for a workably competitive industry is that reductions in cost be necessarily passed on to the consumer as corresponding price reductions. This is the point at which the available evidence on the relationship of drug costs to prices should be assembled. First, the cost evidence presented so far to the Committee will be evaluated, and then other cost and price data relating to the Canadian market will be considered in conjunction with the cost-price relationships developed for the United States during the Kefauver hearings.

The Hoffman-LaRoche submission to the Committee consists chiefly of an attack on the Canadian patent law and an indictment of several small firms which applied for compulsory licenses, in the course of which some interesting data on costs and prices is divulged. At best, this data is approximate and gives only rough orders of magnitude, but it is worth examining. The submission relates that Bell-Craig, in its application for a compulsory license for chlordiazepoxide (the so-called "Librium") maintained that while it could not estimate its probable cost of manufacturing the drug very accurately, this was largely irrelevant to the selling price. Roche agreed without comment. (15a). The implication is clearly that prices need not be related to costs, and that cost is so small relative to price that substantial variations in cost would have no significant effect on expected profit margins.

Roche contended, but did not explain, that the minimum price for this drug could not go lower than $1300 per kilogram, which is presumably the minimum supply price representing cost plus the minimum acceptable profit. (15b). Roche estimated Bell-Craig's price for the drug when sold in dosage form at $3000 per kilogram; Bell-Craig estimated

that it would probably sell no more than 60 kilograms per year. Roche indicates that it sold in Canada 3424 kilograms of the drug through 1965; since it was first introduced in 1960, average sales per year for Roche were about 685 kilograms, or about 11.4 times as great as Bell-Craig's expected sales. (15c). Roche further stated that its average price received per kilogram was $4400. Presumably this is the cost to the retailer; if the druggist adds to this a 2/3 markup and then superadds a dispensing fee, we might be safe in roughly doubling the cost (as is consistent with the submission of the Canadian Pharmaceutical Association to this Committee, see Appendix A to the present submission) and obtaining a cost of $8800 per kilogram to the consumer. But what is the factory cost to Roche and to Bell-Craig? Roche feels that Bell-Craig would be no longer interested in producing if the price falls to $1300 per kilogram, (7hh) but the $1300 itself may include some rate of return on investment. If it is in the neighborhood of 25% on sales price, before taxes (as would not seem unreasonable in view of the small outputs contemplated by Bell-Craig) then the production cost plus other business overheads would be about $1000 per kilogram. Since Roche produces over 11 times as much in the Canadian market alone, its costs of production are surely much less than this, perhaps on the order of $500, or 50% of Bell-Craig's costs for the smaller output. (Roche indicated agreement with both Bell-Craig's and Empire's admissions that their costs of production would be substantially higher per unit than those of Roche, because of smaller volume of sales.) (15d). As a very rough comparison, then, for which no accuracy can be claimed, Bell-Craig was proposing to sell for $3000 a drug which it could produce for $1000--a markup over production cost of about 200%. If druggists sold Bell-Craig's product for $6000, the constructive total markup over cost would be 500 per cent. For Roche, production costs of roughly $500 would contrast with revenues of $4400, a markup of 780 per cent relative to Roche's revenues, and constructively 1660 per cent relative to price to the consumer. (Naturally the druggist does not impose a 1600% markup; his markup is only 100 per cent. The constructive markup over cost at retail is

computed only in the interest of contrasting production cost and consumer price.)

In another application for license, Delmar indicated that its price for selling the bulk drug would be $450 per kilogram. For a small volume operation, perhaps half of the price would have to be profit in order to provide an acceptable rate of return on the appropriate investment, so that the cost of manufacturing the bulk chemical, before profits might be somewhere in the area of $225 per kilogram. If the profit rate were only 25%, the cost would still be merely $337.50 per kilogram. If we assume that Roche's production costs were about half of Delmar's, we obtain a range of from $112.50 to $168.75 per kilogram. Even if it were as much as $200 per kilogram, there would still be a gap of $300 between estimated bulk drug production cost, and the estimated factory cost of $500 per kilogram. Is a $300 per kilogram margin for preparation of dosage forms reasonable? Roche does not indicate the dosage form mix contemplated in terms of its receipts of $4400 per kilogram. However, if we assume that the kilogram is embodied in 100,000 capsules of 10 milligrams each, some rough indication of the cost of capsuling is indicated by Strong Cobb Arner's quotation of $1.70 per thousand tablets for making tetracycline hydrochloride, where the basic drug and the empty capsules are supplied. (16a). This would be $170.00 for 100,000 capsules. That the order of magnitude is reasonable is apparent when it is realized that the contract price quoted surely includes a substantial allowance for profit. On the other hand, some allowance for losses during dosage form preparation should be made, as well as for the costs of capsules and perhaps other containers, plus the possibly higher costs of preparing other dosage forms.

When Empire requested a license on Roche's diazepam (the so-called "Valium"), the applicant estimated manufacturing costs of about $68 per kilogram, which, with the addition of "overhead and profit" would allow it to sell to others in bulk at $170 per kilogram. (15e). The nature and the amount of the overhead is not specified; presumably the

overhead is manufacturing overhead; if not, the full production cost may be only $68 per kilogram. Let it be assumed, however, that the production cost is in the realm of $100 per kilogram. If Roche's cost is only about half this great, a manufacturing cost of $50 per kilogram is to be compared with Roche's average revenues of $10,000 per kilogram, and the presumable price to the consumer of $20,000 per kilogram. With so low a production cost, the margin of error in cost estimation matters relatively little. If we assume that Roche's other factory costs--tabletting and packaging, etc.--are $300 as is the estimated instance of chlordiazepoxide, the cost per kilogram is only $350. This estimate could be off by about 2/3 and the factory cost of $1000 would still be only 10 per cent of the revenue realized--a 900 per cent markup at wholesale and a 1900 per cent markup at retail. If the lower cost figure is correct, the markups are closer to 2800 per cent and 5700 per cent respectively. There would seem to be some room for price reductions. Empire planned to sell at prices about 40 per cent below those of Roche, and with its lower cost structure it could probably reduce prices much farther.

Let it be stressed that these markups quoted are estimated markups over factory cost only, and not net profit margins. What they measure is the gap between the cost of production and the price to druggists and to consumers. The gap will be filled in part by costs of distribution and general and administrative overhead. Research and development may also add to the total. But this still leaves a lot of room for sales promotion and profits. In a competitive industry the gap would not be nearly so pronounced.

Two other observations were made on the costs of chlordiazepoxide. Roche cites Micro's admission that its costs of making the bulk drug would be about $460 per kilogram (15f) which compares closely with Delmar's estimate of $450. But Mr. Leslie Dan of the Canadian Drug Manufacturers quoted costs for this substance of $150 per kilogram in Switzerland and $81 in Italy. (7d). In view of these foreign prices, it

seems quite likely that Hoffman-LaRoche, a Swiss-based firm, could make the material in Switzerland at a cost of under $150 per kilogram. Transportatio costs should be negligible, and the addition of customs duties should not increase the cost to over at most $200 per kilogram. Hence the earlier estimate of $500 total cost of preparing finished dosage forms seems reasonable, when taken in conjunction with Mr. Dan's statement that costs of preparing dosage forms run between $1.00 and $2.00 per thousand capsules.

Professor George Wright, in his brief, "Canadian Drug Patents," refers to an unnamed drug which has similar costs: the patent holder claims a value of $3,528 per kilogram, while the licensee contests that it is $150, and Dr. Wright observes that the drug can be bought from Europe for $72.00 per kilogram. He gives a further example: pentaerythritol tetranitrate sells under a brand name (presumably Warner-Chilcott's "Peritrate") for about $2.70 per hundred tablets to the druggist, and presumably is dispensed for about $5.40 per hundred 20 milligram tablets. A Canadian-owned company (presumably Empire, Dr. Wright's company) is quoted as selling under the generic name at a price of 55 cents at wholesale, and presumably about $1.10 to the drug buyer. The cost of the latter is said to be 21 cents per hundred; the cost of the more expensive version might be as much as 26 cents. The brand name firm imposes a markup over production cost of 940 per cent to the druggist, and the markup above the retail price is presumably 1980 per cent. The generic seller's markup over factory cost is 162 per cent, and the equivalent retail price is equal presumably to a 424 per cent markup. Interestingly enough, the brand name version is not patented, and both firms buy the raw material from the same supplier. What accounts for the price difference? Dr. Wright submits that it is inefficiency. For an unpatented drug, it probably depends upon sales promotion efforts aimed at brand name prescribing, which it may be argued falls within the category of inefficient use of resources.

This would seem to be a comprehensive review of the sum total

of data on production costs (rather than prices or aggregate balance sheet breakdown) relating to particular drugs, which has so far been presented to this Committee. This fact speaks for itself. (I will add any available later information in later drafts.)

The only other available data on drug production costs in Canada comes from the Green Book and relates to cost levels as of 1958-1959 (2c). Most of the data given represent not actual factory production costs, but instead costs of the bulk chemical as imported. It is instructive to survey certain of these reported costs or import prices and compare them with the revenues received from sales of finished dosage forms as of 1958-1959 prices and 1965 prices. (The latter comparison is of interest only to the extent that 1965 production costs are related to 1958-1959 production costs.) Because of the large possible margins of error associated with making estimates related to these data, and because the material is not necessarily up to date, only a few drugs will be analyzed with respect to the cost-price relationship. These drugs consist of those for which cost data were obtained and published in both the Green Book and the Kefauver Subcommittee Report: chloramphenicol, tetracycline, and meprobamate.

Although the "broad-spectrum" antibiotics all sell at virtually identical prices, production costs appear to differ greatly, at least on the basis of available cost information. Chloramphenicol seems to be the lowest in cost, it being possible to produce this drug synthetically rather than through fermentation. The Green Book cites that reported costs of manufacture of the drug in Canada in 1958-1959 were about $90 per kilogram, although it is not clear whether this cost refers to the operations of Parke-Davis, of Fine Chemicals, or to both operations. Fine Chemicals sold the bulk drug to other manufacturers for $200 per kilogram plus a royalty which at that time had not been determined. Imports from Europe during 1959 were reported at prices between $60 and $250 per kilogram, excluding duty. (2d). Since chloramphenicol is sold in 250 milligram capsules, one kilogram of the

drug should yield 4000 capsules. With a liberal allowance of 5 per cent for wastage in processing, a kilogram should still suffice for 3800 tablets. At this time, Parke-Davis was selling 100 capsules to the druggist for $34.02, and the druggist was presumably retailing this quantity for about twice this sum, or $68.04. Hence a kilogram in dosage form would yield a revenue of $1292.76 to the manufacturer, and $2585.52 to the retailer. The estimated production cost in Canada was $90 per kilogram; the factory cost, however, would include tabletting and packaging costs. Data on these costs were not obtainable in the <u>Green Book</u>; however a computation of these costs was made by the Kefauver Subcommittee staff and applied to chloramphenicol. (4j).

It is of interest to look in some detail at the Kefauver Subcommittee staff's estimate of Parke-Davis costs for a 100-capsule bottle of 250 milligram chloramphenicol capsules. Parke-Davis in 1960 had a contract with Farmitalia of Italy under the terms of which it was to buy up to 30,000 kilograms of this drug at a price of $30 per kilogram. Since only 6,000 tons had been purchased under this contract through July 11, 1960, it may be inferred that the buyer found he could make the drug more cheaply in Detroit--that is, at less than $42 per ton, since the import duty was apparently $12 per ton. To this raw material cost, the Subcommittee staff added actual cost data for capsuling and packaging tetracycline capsules, as reported by Upjohn: for a bottle of 100 capsules, capsules and other materials would cost 17 cents; production labor and overhead, 13 cents; packaging materials, 6 cents; packaging labor and overhead, 5 cents, for a total of 41 cents. For Parke-Davis's capsules actually made from the Italian bulk drug, estimated costs per bottle of 100 were 79 cents for raw materials, 41 cents for finishing and packaging, and 32 cents for the import duty, a total of $1.52 per bottle. (If production costs in Detroit were $42 per kilogram the costs for the production of chloramphenicol from domestic United States produced chloramphenicol would be the same as for Italian bulk raw material produced drugs.) This $1.52 per bottle of 100 tablets is

a cost only 5.0 per cent of the wholesale price of $30.60 in the United States, and 3.0 per cent of the retail price of $51.00. It would be only 5.5 per cent of Parke-Davis's claimed average revenue of $27.50 per bottle. Even if the cost of making the drug in Detroit were twice as great as the Italian price, a cost of $60 per kilogram would still increase costs to only $1.99 per bottle.

Turning now to Canada, let us assume that because of the smaller volumes produced, it cost Parke-Davis $90. per kilogram to produce the drug. (Fine Chemical's output must have been considerably less than that of the patent-holder; if the $90 cost stated in the Green Book refers to Fine Chemical's cost, that of Parke-Davis could have been substantially lower.) If we assume that finishing and packaging costs in Canada were the same as in the United States--41 cents per hundred tablets, or .41 cents per tablet, then the total factory cost of chloramphenicol would be $105.58 per kilogram (3800 tablets). The sales revenue at the wholesale price level at that time of $1292.76 would imply a 1125 per cent over factory cost; the retail price would imply an equivalent markup by both manufacturer and retailer of 2350 per cent over factory cost.

It is interesting to note that Fine Chemicals found it necessary to sell for $200 the kilogram of chloramphenicol which it had produced for perhaps $90; this gives some support to the estimates mentioned above of assuming that about half the sales price of a drug by a small firm would be the necessary profit margin. For firms which bought chloramphenicol at $200 per kilogram and then experienced finishing and packaging costs of .41 cents per capsule, the total cost of producing 3800 capsules from the kilogram would be $215.58; when sold to the retailer at $1292.76, and resold by the retailer at $2585.52, the implied markups over factory cost would be 500 per cent and 1100 per cent, respectively. Since 1960 chloramphenicol prices have declined, in part no doubt because of compulsory licenses granted under section 41(3) of the Canadian Patent law, and the June 1965 price levels

for the drug would result in total revenues of $896.80 per kilogram as sold to the druggist and $1793.60 as sold to the consumer. The implied markups over factory costs are now 317 per cent, and 734 per cent, respectively. (This of course assumes that factory costs are still the same today, which is probably not the case. Costs may have increased or decreased, depending upon whether or not possible increases in price levels for materials purchased have been offset by possible improvements in methods of production.)

For tetracycline, the Green Book reports a wide range of costs. Bristol imported the bulk drug from its United States parent company at prices of $90 per kilogram in 1958 and about $140 per kilogram in 1959. Bristol sold to Squibb and Upjohn at prices reported by the buyers as $336.57 for Squibb and $414.50 for Upjohn. Pfizer imported its drug from its United States parent at prices ranging from $156.71 to $525.36 per kilogram. Cyanamid reported production costs in its Canadian plant of $644.15. Gilbert imported the drug in bulk for $300 per kilogram. (2e). It is impossible, without further information, to reconcile these various figures. Royalties play an unknown, but probably significant, role. The Green Book suggests that the costs reported are accurately reported, and that Bristol's costs show that tetracycline can be manufactured at costs relatively quite low in comparison with some of the reported costs. One might conclude that where prices are extremely high relative to factory production costs, a very wide range of costs are consistent with profitable operation.

Fortunately, in the Kefauver hearings, Bristol's actual production costs for tetracycline were made public. A bottle of 100 capsules of 250 milligrams each cost only $1.67 to produce. If 41 cents of this total is alloted to finished and packaging, the cost of the drug itself is $1.26; hence the drug cost in 3800 capsules should be $47.88, which is Bristol's equivalent factory cost of one kilogram of tetracycline when converted into capsules with a 5 per cent wastage allowance. Bristol also paid $1.03 royalty to Pfizer on a 100 capsule bottle, but as mentioned above, while the payment of the royalty increased

Bristol's cash expenses of doing business in tetracycline, royalties paid do not constitute a cost of production but are more in the nature of a levy on product profitability. Bristol's total expenses, including royalties, would be $102.60 for 3800 capsules which would sell in the United States, at prices current at that time, for $1162.80 to pharmacists, and for $1938.00 to consumers. This is equivalent to a markup of 1033 per cent over factory costs plus royalties in the price to the retailer, and an implied markup of 1789 per cent by the pharmacist over the factory cost plus royalty.

In Canada, the bulk drug prices paid which were reported ranged from Pfizer's $156.71 per kilogram for imports, to Cyanamid's $644.14 reported production cost per kilogram. Assuming that Upjohn packaging and finishing cost of $.41 per hundred tablets can be applied total factory costs per kilogram would be $172.29 for Pfizer's lowest import costs, and $659.73 for Cyanamid's production cost. In terms of 1959 prices, Pfizer's markup over factory cost would have been 650 per cent (with the retail price representing a constructive 1400 per cent markup); Cyanamid's only about 100 per cent (300 per cent at retail). Since Pfizer's patent was declared invalid by the United States FTC in 1963, considerable price competition has developed in this drug in North American markets, and the Canadian price had fallen by 1965 to $18.00 per bottle of 100 capsules of 250 milligrams each to the druggist. Current cost levels in Canada are almost impossible to estimate. Canada Pharmacal recently quoted a price of $30.30 per thousand 250 milligram capsules of tetracycline. Total revenue per kilogram would accordingly be no more than $115.14 which would be an absolutely maximal estimate of the firm's factory costs (See Appendix D, page 1.) In 1965 the price of 3800 capsules of tetracycline to the retailer was $684.00 and presumably twice that much to the buyer at retail. Hence the presumed maximum cost was such as to yield a markup of 494 per cent over maximum estimated factory cost on sales to retailers; the retailer's price was such as to yield a constructive markup of 1088 per cent over maximum factory cost.

The only other drug for which records of both Canadian and United States costs are available is the tranquilizer meprobamate. The Green Book indicates that the price of the drug varied between $6.00 per kilogram and the $29.12 at which one large firm purchased from its United States parent company--an example of the extent to which intercompany-transaction prices can artificially diverge from market prices. (2f). One kilogram could yield 2500 tablets of 400 milligrams each. Allowing for a wastage of 2 per cent, 2450 capsules would be the net output. At a price of $6 per kilogram, the packaging and finishing costs of $8.33 for 2450 tablets would bring the factory cost up to $14.33 per kilogram, neglecting any royalties which might be due. The packaging and finishing costs are based on the tabletting charge of $2.00 per thousand the the bottling charge of $1.40 per thousand, as given in the Report of the Kefauver Subcommittee. (5c). The prices charged to the druggist for a bottle of 500 capsules of 400 milligrams each varied from Ayerst's $31.50 to Empire's $7.50. (2g). Ayerst's total revenue would then be the equivalent of $154.35 per kilogram while Empire's would be $36.75. Assuming that a seller could obtain the drug at $6 per kilogram and sell it at Ayerst's price, the markup over factory cost would be 977 per cent; if sold at Empire's price, only 156 per cent. The constructive markups at retail over factory cost would be 1854 per cent and 412 per cent respectively. Assuming that one may compare these costs with prices of from $26.25 (Horner) to $3.75 (Empire) to the druggist in June, 1965, the markup over cost would be 798 per cent for Horner and only 28 per cent for Empire. At retail, the constructive markups over factory cost would be 1696 per cent and 156 per cent.

These estimates of the relationship of prices to costs are presented simply because there is a need for such a comparison, there are no other data available on which to base such a comparison, and it is preferable to make the most of the existing data rather than to present no cost-vs.-price evidence whatsoever. The relevance of the costs of 1959 to the prices of 1965 is simply unknown. What is of interest

is to note that factory costs may be less than ten per cent of the price to the druggist on the basis of these estimates; even if actual costs were twice as great, they would still be one-fifth or less of the price--a truly remarkable ratio in view of the experience of other industries. Of course it is true that not all products sold by drug firms have such large gross profit margins; furthermore, gross profit margins exceed net profit margins because of the necessity of incurring other expenses than factory costs. Nevertheless, it would be impossible under efficiently competitive conditions for <u>any</u> significant drug to sell for very long at prices ten times or more in excess of production costs; and it may be contended that the types of expenditures which fill in almost the entirety of the gap between the gross profit margin and the net profit margin are largely wasteful and are expended chiefly in order to keep the gross margin unnecessarily wide rather than to perform essential production and distribution functions.

An approximation of the gross margin of a drug firm may be obtained by comparing the cost of goods sold to total sales revenue. Unless the firm's income statement can be carefully audited, the economist cannot be certain whether costs and revenues are being appropriately allocated or otherwise accounted for. Nevertheless, if we consider the 1965 income statement submitted to this Committee by Smith Kline & French, it appears that <u>only about 16 per cent</u> of sales revenues were accounted for by the actual cost of goods sold. By way of contrast, sales promotion outlays were about 38 per cent of sales, and research and development only about 7 per cent. (7e). To be sure, other companies may have higher ratios of costs of goods sold to sales revenues. But one cannot be confident that unadjusted income statements provide a sufficiently precise measure of the ratio of the exact factory and other genuine production costs incurred, to the precise sales revenues obtained from selling these particular drugs. This is particularly problematic when dealing with the operations of international companies. For example, Parke-Davis claims that its 1965 cost of goods sold was 47.5 per cent of sales revenue for its Canadian operations, (7f),

but in its submission it includes its 1965 Annual Report to stockholders, which indicates that the cost of goods sold ratio for all operations in all countries was only 36.3 per cent of sales. The discrepancy is sizeable and one may infer that it is advisable to interpret financial statements of domestic subsidiaries of foreign parents with considerable caution. In other submissions to this Committee, Frosst indicated a ratio of 29.8 per cent (7g) while Roche designated 61.7 per cent of sales as the "cost of sales" which includes everything except research and development, administration, and royalties and interest charges, and hence includes an unknown component of sales promotion and other costs. (7h).

Even allowing for differences in definitions and measurement, the statistics presented to the Committee on "Key Business Ratios in Canada" in 1965 from Dun and Bradstreet of Canada, Ltd., (7i) show that the ratio of the cost of goods sold to sales is lower in the drug industry than it is in any of the fifty other manufacturing industries listed, with the single exception of soft drinks. The drug industry ratio of 49.1 per cent is 36 per cent lower than the ratio of 73.7 per cent for all manufacturing firms, and 26 per cent below the ratio of 69.1 per cent for all companies grouped together. This large gross margin also permits a relatively quite high ratio of profits to tangible net worth (preferred and common stock plus net surplus minus intangibles): 21.93 per cent, which is the sixth highest ratio among the 51 industries listed. Since a total of 224 firms were included in arriving at the ratios for the "pharmaceutical preparations" industry, it is likely that the relatively higher cost of goods sold ratios for the smaller firms increased the industry ratio to 49.1 per cent, a level which may be above that of the average of the largest firms considered as a group. Conversely, the inclusion of the smaller firms may have had a depressing effect on the ratio of profit to tangible net worth.

Further indications of the low level of production costs relative to prices may be obtained by a study of the relationship of prices to the druggist and bid prices in competitive bidding for sales to hospitals and public agencies. As investigations in both Canada and the United States have shown, competitive bidding may very greatly reduce the price of unpatented drugs, or drugs the patents for which have been widely licensed, while reductions in price for patented drugs are typically very slight. In the United States, the Military Medical Supply Agency has been able to purchase a bottle of a thousand 25-milligram tablets of the tranquilizer reserpine for as little as 51 cents, while the price of the patent holder, CIBA, was $39.50 to the druggist. CIBA itself when questioned by the Kefauver Subcommittee about this price spread, claimed that it had not recovered out-of-pocket costs on its low bids, but this is hard to accept, particularly in view of CIBA's subsequent even lower bids. Later during the Kefauver hearings, McKesson and Robbins indicated that its full cost of producing for this drug was 63 cents; the larger volumes sold by the patent holder might have enabled it to experience costs lower than 50 cents. (11, p. 215.)

In Canada, the Green Book shows that the University Hospital in Edmonton, in response to tenders in 1959 was able to obtain a 43.2 per cent discount off the regular hospital price (which in turn was about 8 per cent below the price to the retail pharmacist) for Bristol's brand of tetracycline for an order of 20,000 bottles. For Schering's brand of prednisone, the discount off regular hospital price (which in this instance already reflected a 49 per cent discount off the price to the pharmacist) was 76.9 per cent, the order size not being specified. In the case of the latter drug, where patent protection had not been obtained, the price to the hospital was only about 12 per cent of the price to the druggist. (1i).

Appendix D to this submission consists of several schedules relating to the prices of certain drugs to various buyers in Alberta in 1966. The drugs concerned belong to four groups; Antibiotics,

Corticosteroids, Ataractics, and Oral Anti-diabetics. The prices given are those quoted by various brand name and generic name suppliers to the University of Alberta Hospital at Edmonton, and in the case of ataractics, to the Alberta Department of Health. Prices are also given, where available, to wholesalers, retail pharmacists, and final consumers. Manufacturing cost data is taken from the Green Book for those drugs for which it was available at that time.

An analysis of these data will reveal several interesting features. Table I, below, indicates the contrast between the maximum percentage discounts off consumer list price allowed on various drugs by brand name and by generic name drugs.[1] For brand name antibiotics, discounts allowed range from 55 to 86 per cent; for generic name antibiotics, the only observation reported shows a discount of only 34 per cent. One reason for the smaller discount allowed by the generic seller is his relatively much lower consumer list price; it should not be assumed that because the discount allowed off list price is smaller for the generic firm, the brand name firm's price is lower. On the contrary, reference to Table II will indicate that the ratio of the lowest price quoted by a generic name drug supplier to the lowest price quoted by a brand name supplier, for purchases by the University Hospital at Edmonton is only 23 per cent in the case of tetracycline.

Table I shows that in the case of corticosteroids, the largest discounts allowed by brand name drug sellers ranged from 46 to 96 per cent; for generic drugs, three observations were recorded, at 29, 40, and 83 per cent. For ataractics, the range was from 43 to 91 per cent for brand name drugs, and from 30 to 39 per cent for generic drugs, on price quotations to the University Hospital at Edmonton. For quotations to the Alberta Department of Health the discounts were larger in all but two instances, ranging from 61 to 91 per cent for brand name drugs. The

---

[1] In Table I, only the maximum percentage discount allowed from consumer list price by one particular seller among all listed sellers of a particular drug is ordinarily listed. To obtain prices for comparable quantities, the per unit price of the quantity closest in magnitude to the basis for the Hospital or Government bid (usually 1000 tablets) is adjusted proportionately.

larger discounts received by the Alberta Department of Health apparently do not reflect larger quantity purchases, since the prices quoted are generally for lots of a thousand, regardless of total order size. It may be due simply to the greater potential bargaining power of the larger agency. For oral antidiabetics, two sellers of brand name preparations of tolbutamide quoted identical discounts of 70 per cent to both agencies, and for phenformin one seller quoted prices implying discounts of 55 and 66 percent to the two agencies. Comparative data for generic sellers of oral antidiabetic drugs are lacking.

Table II shows that in no instance did the lowest price quoted by the brand name supplier undercut the lowest price quoted by a generic name supplier as far as the data in Appendix D are concerned. For tetracycline, tolbutamide, and meprobamate the lowest generic price was only about one-quarter as high as the lowest brand name price. For dexamethasone, promazine, and prednisolone the generic prices were respectively about two-fifths, three-fifths, and four-fifths as high as the brand name prices. Only in the case of prednisolone did the brand name price closely approach the level of the generic name price.

Table III shows the ratio of the manufacturing cost for a drug reported in the <u>Green Book</u> to the 1966 list price to the consumer, for 15 brand name drugs, 13 of which are sold by major firms. As mentioned before, the degree of comparability between the price and cost data is unknown because of the time elapsed since the cost data were compiled. Table III shows that the range of manufacturing costs as a percentage of consumer list price is from seven-tenths of one percent to 31 per cent, with a median of 12 per cent. Seven of the ratios have a value of less than ten per cent, five lie between 11 and 20 per cent, two between 21 and 30 per cent, and the highest is 31 per cent. Table III does not necessarily constitute a representative sample of prescription drugs, but consists instead of a listing of cost price data for all drugs for which cost data is given in Appendix D. except for those drugs previously discussed

TABLE I

I. BRAND NAME DRUGS:

Name of Drug	Name of Firm	Maximum Percentage discount from retail list price allowed to purchasing agency: (1966) University Hospital Edmonton per cent	Alberta Dept. of Health per cent
Antibiotics:			
Erythromycin	Abbott	68	
"	Lilly	55	
Novobiocin	Merck	55	
Tetracycline	Nadeau	86	
Chlortetracycline	Lederle	77	
Chloramphenicol	Intra	77	
Cycloserine	Roche	77	
Corticosteroids:			
Prednisone	Schering	96	
Prednisolone	Schering	91	
Triamcinolone	Lederle	55	
Dexamethasone	Merck, Schering	52	
Methylprednisolone	Upjohn	46	
Tranquilizers:			
Promazine	Mowatt and Moore	91	91
Chlorpromazine	Poulenc	80	84
Trifluoperazine	SKF	49	
Hydroxyline	Pfizer	51	
Tranylcypromine	SKF	46	65
Thioridazine	Sandoz	57	67
Triflupromazine Hcl	Squibb	46	70
Phenylzine Dihydrogen sulfate	Warner-Chilcott	43	61
Meprobamate	Wyeth	68	60
Promethazine	Poulenc	59	68
Prochlorperazine	Poulenc	50	68
Chlordiazepoxide	Elliott-Marion	68	
"	Roche	63	67
Diazepam	Roche	55	63
Oral Antidiabetics:			
Tolbutamide	Hoechst; Horner	70	70
Phenformin	Arlington-Funk	55	66
II. GENERIC NAME DRUGS:			
Antibiotics:			
Tetracycline	Gilbert	34	
Corticosteroids:			
Prednisone	British Drug Houses	83	
Prednisolone	Bell-Craig	40	
Dexamethasone	Gilbert Gil	29	
Tranquilizers:			
Promazine	Gilbert	30	
Meprobamate	Gilbert	39	

Source: Appendix D.

TABLE II

Ratio of lowest price quoted by generic name drug supplier to lowest price quoted by brand name drug supplier, to the University Hospital, Edmonton, Alberta, 1966

Tetracycline	23 per cent
Prednisolone	81
Prednosone	97
Dexamethasone	42
Promazine	65
Tolbutamide	28
Meprobamate	25

TABLE III

Drug	Producer	Ratio of Manufacturing Cost Reported in Green Book to 1966 List price to consumer
Antibiotics:		
Erythromycin	Upjohn	12 per cent
"	Merck	29
Cycloserine	Roche	30
"	Lilly	31
Tranquilizers:		
Promazine	Wyeth	9
"	Intra	15
"	Mowatt and Moore	18
Chlorpromazine	Poulenc	15
Perphenazine	Schering	7
Trifluoperazine	SKF	1
Hydroxyline	Pfizer	0.7
Thioridazine	Sandoz	17
Triflupromazine	Squibb	9
Meprobamate	Wyeth, Horner	4

These lower prices to hospitals and public agencies reflect several factors: (1) certain economies of large scale selling, such that some costs are reduced for such transactions; (2) the hospital's exemption from federal sales tax in itself should allow hospital prices to be reduced by about ten or eleven per cent below the price to the druggist; and (3) the presence of potential price competition among sellers, which usually becomes effective to the extent that small generic-name sellers are able to compete with the large firms. Usually this is possible only in the absence of patents.

It has been argued that sales to pharmacists at high prices make possible the sales to public agencies at lower prices, and hence the former sales "subsidize" the latter. If by this it is meant that the latter sales are actually made at a loss, then I believe the contention to be generally incorrect. Production costs are apparently so low that very substantial reductions can be made without eliminating profits. Furthermore, a company can always add to its total profits by selling goods at special low prices, provided that these prices are above marginal or out-of-pocket costs incurred in order to make the sale, and further provided that the lower prices received on the particular transaction do not affect prices received in other markets. To the extent that firms have excess capacity they may be more keenly motivated to increase the rate of output and spread the overhead cost of excess capacity over a larger level of production by taking special orders at price levels exceeding out-of-pocket costs incurred by such orders.

Again, if costs of making sales through hospitals are lower than through druggists because of large unit purchases, then there is no discrimination between distribution channels if the same general schedule of quantity discounts is available for both types of distributors. (Discounts offered do not have to be identical, since hospital sales may involve cost savings over and above those relating to quantity purchased alone.) On the other hand, the exemption of hospitals

from sales tax does act to discriminate between distributive outlets--but this is not due to actions taken by the drug firms. Still, price differentials may easily exceed those which would be due to the combined effects of large quantity orders and sales tax exemption. But the seller who charges the highest price he can obtain in two separate markets is not necessarily subsidizing one market at the expense of the other because he can exact a higher price from one type of buyer than from the other. In economic terms he is just taking advantage of the separation of the two markets to discriminate in price between buyers. If he cannot make a profit in one market, there is no reason why he should lose money just to subsidize it, when he can simply refuse to bid at competitive levels--as many large firms apparently do in the bid markets. (The contention that firms are willing to lose money on bids in order to get their drugs used in hospitals and convince physicians of their quality is probably to be rejected as a rationalization for low bids. The myriad of other sales promotion activities will ensure that the doctors become aware of all brands.)

The bid market is separated from the retail prescription market in that public agencies which buy drugs at low prices do not resell them at slightly higher prices to pharmacists. The demand for drugs on the part of retail pharmacists is derived from the demand of the drug buyer, which of course is extremely inelastic with regard to price. Retail pharmacists can afford to pay high prices because they can charge high prices to buyers, in the interests of maximizing profits. The demand on the part of hospitals and other public agencies is differently constituted. Being non-profit agencies, they operate within a general budget, and while they are not directly concerned with selling individual items in accordance with scales of particular charges, they are concerned with lowering total operating costs and keeping within budgets. Their purchasing agents may also take a professional interest in economical buying. But the most important distinction between the demand for drugs on the part of the retail pharmacy and the public agency is that the latter can solicit price competition among sellers, while the former have little ability to do so, and also relatively

little interest because they can readily pass on higher prices to drug buyers. With demand much more elastic in the bid market, drugs produced at a given cost level will sell at prices much closer to costs. With certain costs lower in the bid market, such as some distribution costs (and the sales tax), supply prices will be lower. Hence with more elastic demand and lower supply costs in the bid market, it is to be expected that bid prices will be lower, to the extent that rival suppliers can be induced to engage in price competition with each other. But if the possession of patents precludes the entry of rival suppliers from the market, the demand situation in the bid market may be as inelastic as in the retail market.

f. Sales Promotion Activities.

Economists are fond of making a distinction between informative (or factual) advertising, and persuasive (and perhaps less than factual) advertising. In an efficiently competitive drug industry, advertising practices and other sales promotion strategies would be adapted so as to take advantage of the structure of information needs and the abilities of the individuals involved to absorb information, in order to minimize the costs of providing the necessary information. The fact that ethical drugs are ethical in the sense that they cannot be bought over the counter, but must be prescribed by physicians would seem to minimize the temptation to engage in advertising since advertising direct to consumers would not be productive of sales. Three characteristics of physicians are also important. They are highly trained at medical schools. They are on the average extremely busy--there are many demands upon their time. And on the average they are very prosperous, with income levels well above the median. Because of his interest and training, the physician is quite capable of appreciating and responding to purely informative technical and factual releases concerning drugs, and need not be enticed and cajoled into responding to the sort of purely persuasive advertising appeal to which so many physicians have publicly objected, and which Dr. Howe of this Committee has declared to be

insulting. (7j)[1]. Since doctors are busy, the time that they can spend in reading and evaluating information on drugs is limited. In brief, it is in the physician's interest in every way professionally, financially, and as a citizen--to keep well informed on developments in drugs. This can best be accomplished by disciplining the flow of information, making factual communications more concise, limiting purely promotional propaganda and superflous communication, and eliminating entirely the possibility of misinformation. Physicians should rely on completely unbiassed sources of information, and since they profit from the availability of good medications, should be expected to pay the costs of being supplied with adequate drug information. Through the purchase of official compendia and subscription to independent newsletters, the conscientious physician could keep abreast of at least the most important developments in his specialty with less time spent and more confidence in the quality of the information conveyed than is now the case.

Drug firms have defended their sales promotion outlays as "postgraduate medical education." But it is inescapable that commercial bias is the fundamental principle informing this "education", and such conditions should be recognized as insupportable. If drug information were provided by unbiassed sources, there would seem to be no purely economic or therapeutic reason for drug firms to incur any sales promotion outlays in connection with physicians as prescribing agents, as long as the firms refrained from engaging in mutually offsetting sales promotion campaigns designed to facilitate rivalry in the absence of price competition. How is adequate drug information to be provided by

---

[1] A rather different view was taken by the Canadian Pharmaceutical Manufacturers Association in their 1961 brief; there is no need to characterize it since it speaks for itself: "Visually, the so-called flamboyant pictorial style used in journal advertisements is not as unusual as it may appear <u>to the uneducated eye.</u> An advertisement to gain readership must be more than a box of black type. It must carry a pleasant layout of copy, and to a higher intellect such as a professional man this layout must be in extremely good taste." (emphasis supplied) (2i).

independent sources? Admittedly, official compendia are published infrequently and hence may not include the latest drugs. Even this may not be a drawback if, as has been suggested, new drugs typically owe their success more to skillful promotion than to true advantages in use. Independent newsletters may be more timely; one such publication, The Medical Letter is already in existence, published in the United States. It has been suggested that such a publication be undertaken under public auspices; such a recommendation was made in the Hall Commission report, and such a publication actually exists in the United Kingdom, where it is made available free of charge to the physician. The latter feature may be desirable in view of the deplorable performance of doctors in the United States, only about 15 per cent of whom bothered to subscribe to The Medical Letter.

No matter how the information service is financed, it will result in savings if it is combined with reforms to lower drug prices and eliminate the ability of drug firms to promote their products as extravagantly as is their custom. The costs of even an elaborate drug information reporting system, such as has been proposed where doctors would be obligated to relay information on adverse reactions to a central data centre, would surely fall far short of present levels of outlays on promotion. At present, drug firms subsidize the physician by providing him with information and propaganda, the bulk of which may be unwanted as well as in varying degrees biassed and misleading.[1] The cost of this sales promotion is naturally passed on to the drug user in higher prices. Hence the physician is subsidized at the cost of the patient, a subsidy not needed by the physician (since he could pass on

---

1 Many examples of misleading advertisements were unearthed during the Kefauver hearings. One of the best came from Upjohn. A circular, "Ulcerative Colitis," was mailed to physicians, featuring two full-page X-ray photos clearly designed to imply a dramatic recovery in a patient before and after the use of the advertised drug. Upon inquiry to the firm's medical director, it developed that the two X-rays were of entirely different persons with qualitatively different disease conditions, neither of whom had even been treated with the advertised drug. (9c).

his own costs of keeping well-informed in his fees charged), largely not wanted, and arguably not justified, since it represents a transfer of income in favor of a high-income group and at the expense of a group whose income is not only on the average lower, but whose ability to pay is reduced by precisely the circumstances responsible for seeking medical treatment: at least temporarily imparied earning ability, and increased expenses. If the physician assumes the costs of keeping himself informed, while these costs will be passed on to the patient, they will be much smaller in total amount than the thousand or more dollars per year per physician which drug firms are said to spend on marketing. If the information services are supplied at public expense, physicians and patients together will be subsidized by the taxpayer, which is at least a less objectionable arrangement than subsidy of physicians by drug buyers alone.

It is plausible to assume that some, perhaps many, of the drug firms themselves are discontented with competitive needs to mount expensive advertising campaigns in order to maintain market position. If these expenses were not made, profits would increase since the drug buyer would in general not have his bargaining power increased by the ceasation of advertising, and there would be no reason to reduce prices just because marketing costs had declined. It is therefore not surprising to learn from the PMAC Submission to this Committee that the member firms are unhappy with their high marketing and distribution costs, and are even interested in the development of an independent medium to disseminate drug information. In this area, perhaps, industry and reformist sentiment are approaching some reconciliation. The development of an independent information system would allow the virtual elimination of drug firm sales promotion budgets. But in itself it would not enforce such elimination. To the extent that it is the profitability of selling drugs at inflated prices which justified and motivates marketing outlays, reforms would be needed to institute genuine price competition which would eliminate excessive profit margins and thus eliminate both the

ability and the desire to engage in sales promotion rivalry. Even under actively competitive market arrangements, selling costs would probably not be reduced to zero, but if they were cut from 30 per cent of the sales dollar to about 3 per cent, then other things being equal, the sales price to the druggist would be cut by 27 per cent. If the druggist has a pricing policy which results in approximately doubling the manufacturer's price, the price to the drug buyer could be cut by the same 27 per cent. But the institution of price competition would be likely to cut profit margins as well, and force a reduction of excess capacity and its accompanying costs, together with reductions in the less productive areas of the research and development budgets. It is not possible to predict how large a reduction in prices may be compelled by drug reform, but the scope of such price cuts is not limited to the size of the sale promotion budget, the most frequent target of drug price criticisms.

It is, however, in the area of marketing activities that the most conspicuous wastes of the drug industry become apparent. Physicians justifiably complain about the great bulk of direct mail advertising. As Mr. Lawrence Wilson pointed out before this Committee, the most unfortunate result of deluging the doctor with attractively printed trivia is making it unlikely for him to be able to detect any valuable information which may be buried in the great mass of propaganda. (7k). Hence, the effect of redundant advertising in increasing drug prices may be less socially harmful than its side-effect of rendering more difficult the enlightened practice of medicine. According to the PMAC Submission, even if we accept the cost categorizations which the manufacturers' own spokesman has devised, sales promotion expenses accounted for 30 cents in the industry's sales dollar, as previously stated. The cost of research accounted for only about 6.7 cents; hence 4.5 times as much was spent on sales promotion as on research. Was this justified? under present market circumstances, certainly so. It is my view that executives in the drug industry, judging by the performance of those who have appeared before investigating committees

in Canada and the United States, are extremely shrewd and astute, and are superlatively capable of managing their firms in the interest of maximizing profits and the value of the stockholders' investments. Hence I take it that it is the experience of the industry that sales promotion is much more effective than research in producing profits--for every added dollar in sales revenue, 30 cents will be expended for sales promotion as compared with about 6.7 cents for research.[1]

There are several reasons for this. First, basic research will be relatively small in amount because of the external economies associated with it. Second, even applied research and product development are relatively unproductive except during the periods following major breakthroughs achieved in fundamental research, so it is not profitable to channel any very large share of available funds into this sort of activity. Third, and probably most important, sales promotion can substitute in large measure for both genuine price competition and for productive research. These points deserve considerable attention.

As was observed by several physicians during both the Canadian and United States hearings, a drug embodying a genuine advance in therapy advertises itself. If highly effective and thus of real value, physicians themselves rapidly spread the news. This was the experience with insulin, penicillin, cortisone, and the sulfa drugs. But, in the words of one of these physicians,

> "the more a drug has to be peddled, the more one begins to wonder why." (9e).

---

[1] In view of these facts, one must admire the persistence of industry spokesmen in asserting that research costs are the reason for high drug prices. It is amusing to note that firms do not allocate the same share of their submissions to this committee to these two activities as they do in budgeting expenditures. In the PMAC brief, of a total of 92 pages of text, 11 were spent on research and 9 on marketing, which adds up to 5.5 times as much emphasis on research relative to marketing in the submission as in the budget. Cyanamid devoted 15 pages to research and 10 to marketing in an 80-page submission, or 23.3 times as much emphasis on research relative to the firm's ratio of expenditures on research to marketing costs. Cyanamid devoted 31% of its sales dollar to marketing and 2% to research.)

Dr. A. Dale Console, former medical director for Squibb, was most explicit about the relationship between unproductive research and the advertising budget:

> "advertising is called upon to make successes of research failures...The problem arises out of the fact that they market so many of their failures." (4q).

Almost any drug will sell, if promoted intensely enough, at least for a while. Drug firms complain of the high rate of obsolescence of drugs, and argue that such risks justify high profit rates. The argument is not irrelevant under present circumstances, but the risks of obsolescence are not inherent but result from the way in which drugs are developed and promoted. High risks do not justify high profits in this instance because the risks and profits are both symptoms of the same disease: sales promotion rivalry substituting for price competition. The chief reason for the high turnover rate among drugs is, I suspect, to be explained along these lines: advertising alone can sell physicians on a drug, if intensive enough, but any number can play at the advertising game, especially when brand names can be used to obscure the relationship between or even the identical nature of nominally unique substances. The greater the accumulated experience with a given drug, however, the more likely it is that its untoward actions will become known. However, if the rate at which new products is introduced is as great as the rate at which publicity is given to the mischief caused by existing products, the sales of the new products will increase as that of the old products declines, so that the total cash flow need not suffer.[1]

On the other hand, as any businessman knows, advertising rivalry can substitute--perhaps entirely--for genuine price competition. Price competition is a good servant to the consumer, but a harsh master to the producer. Hence sellers tend to avoid it as much as possible under normal circumstances, and it generally prevails only where it is

---

[1] In the United States, brand-name sellers had to be compelled by law to give proper prominence to generic names in advertising. But brand-name sellers do have their uses for generic names. A firm, for example, may advertise by brand name, but issue warnings under the generic name only. Pfizer and Wyeth adopted this opaque tactic for a triacetyloleandomycin warning. (9f).

forced upon them by the structure of the market: numerous small sellers, none dominant; no collusion; no barriers to entry of new firms or expansion of existing firms. Where sellers are fewer and larger; where barriers exist to entry by new firms; where legal devices exist to facilitate a community of interest in price and production policies--under these circumstances, the forces which compel producers to undertake active price competition will be so weakened that rival firms will attempt to maintain or enlarge their share of various product markets by raising costs instead of lowering prices.

Advertising is inherently less destabilizing an arrangement than price competition. Some segments of the market may be loyal to a given brand even in the absence of advertising; other segments can be induced to prescribe only by increasingly provocative sales appeals. In general, sales can be increased by increasing advertising coverage, attracting new buyers while retaining the old, and perhaps even reinforcing their allegiance to the product. In the case of price competition, however, even though there may be a substantial segment of the market which is not highly price-sensitive and would buy the product at relatively high prices, in order to attract additional and price-sensitive customers, the prices which all customers pay must be reduced. Under such conditions, the controlling considerations relate to the price sensitivity, or price elasticity, of the total market demand for the product, and the expected price elasticity of the net demand schedule which the prospective price-cutter estimates that he will face after all his rivals have consummated their reactions to his price reduction. Only if demand promises to be quite sensitive, or relatively elastic, in response to price reductions, will a particular rival feel justified in gambling on a price cut. Even so, one or two moderate price reductions will ordinarily be sufficient to traverse the region of sufficiently elastic demand and hence to exhaust the possibility of further consumer-benefitting price reductions by the rivals.

The major difference between the two strategies is therefore that price competition benefits consumers through lower prices and higher output, while it reduces the profit levels of producers to competitive

rates--an outcome consistent with maximum efficiency of resource allocation in an economy. But rivalry in extravagant marketing campaigns raises costs and prices, benefits advertising media at the expense of consumers, and possibly also at the expense of company profits, and keeps the total consumption of the products of the industry at relatively low levels. In fact, the effects on profits of the two strategies may be the same in the long run: initially high rates of return on investment serve as a stimulus to efforts to increase output and market share; price reductions will directly reduce profits to equilibrium competitive levels; increased advertising budgets, which are mutually offsetting in the same way as competitive price reductions, except that they do not reduce costs to consumers and increase quantities produced and consumed, may eventually reduce profits to no more than competitive levels. Hence, monopoly prices may not necessarily mean monopoly profits, but simply excessive sales promotion budgets. A monopolist does not always make monopoly profits--he does so only to the extent that he is efficient, and one of the great attractions of monopoly is that it reduces or largely eliminates the penalties which a competitive market imposes on inefficiency.

It should be noted in passing that while price competition benefits consumers and while advertising rivalry may benefit no one except to the extent that it attracts more resources into the advertising industry, it is not suggested that monopolistic rivals are motivated by the desire of private gain at the public expense, while competitive producers are motivated solely to serve society. The producers' motivations do not differ. Competition is always a competition in the hope of establishing a monopoly, but where the structure of the industry rules out the possibility of monopoly, the ambitions of competitors must fail of fulfillment. The task of public policy is to adapt market structures in such a way as to preserve the vigor of competition while securing the public against the dangers of monopoly power on the part of the too-successful competitor.

But in the marketing context of the drug industry, excessive sales promotion budgets serve still another important function, in addition to bolstering the market appeal of products of indifferent quality, and substituting for price competition: they create a major barrier to entry. In most industries where the market is shared by a relatively small group of non-competitive rivals, the number is kept small by virtue of the economies of large-scale production, such that the capital requirements for new entry into the industry on a sufficiently large scale to permit efficient low-cost mass production are in themselves a formidable barrier to entry. In drugs, the bulk powder of the active ingredient in unpatented drugs can often be obtained or produced at very low cost, and certain finished dosage forms can be prepared and sold at prices no more than about ten per cent as great as the prices which the major brand-name firms are able to impose. But the nature of the prescription drugs market is such that the availability of these lower-priced drugs must be brought to the attention of the prescribing physician. Here is a case where merely informative, as opposed to persuasive, advertising is needed. But the vast scale of advertising by the major firms tends by its very bulk to obscure the existence of informative price lists sent out by small firms who do little if any advertising.[1] Hence, the drug firms have created economies of large-scale marketing where none exist in production, and by this means have prevented the products of small lower-priced generic name sellers from coming to the attention of the physicians.

This is serious enough. But there is yet another way in which massive sales promotion puts the small firm at a disadvantage. Eventually, the existence of reasonably-priced drugs may come to the

---

[1] Mr. Seymour Blackman of Premo Corporation testified during the Kefauver hearings that his firm had tried to market its products in competition with major firms, but the contest was an unequal one, since his modest sales promotion efforts attracted no more attention than might be given to "a spark in a vast conflagration" of advertising messages. (4k).

attention of the physician, and he may wonder how it is possible for a tiny firm to undersell a giant by perhaps a ten-to-one price ratio. Here is where the large firm has a great advantage. One reason why major firms spend so much on travelling salesmen (detailmen) is that their sales messages, unlike those contained in journal and direct mail advertising, are not communications of record.[1] The testimony given by several physicians and medical educators during drug industry hearings in North America leads one to suspect that one of the most indispensable functions of detailmen is their ability to disparage, with relative impunity, the quality of the products produced by small generic-name sellers. I say "with relative impunity" because disparagement of the quality of a competing product is considered illegal, not only under common law, but specifically under the Trade Mark Act in Canada and under Section 5 of the Federal Trade Commission Act in the United States, where "unfair methods of competition in commerce" are prohibited. This sort of activity could not be carried on as safely or effectively through the media, of communications of record. This may be one of the major reasons why major drug firms spend about as much on detailmen as on all other types of sales promotion combined. (6d).[2]

---

[1] During the Kefauver Hearings, Dr. Frederick Meyers of the University of California Medical School testified as follows regarding the names in which drug firms adapt sales promotion strategies to the opportunities offered by different media:

> "they conform to the minimum standard of the medium being used at the time. If a medical journal has a certain standard they will meet it, their detail men, their salesmen who are subject to no such discipline, will slide down a few notches, for example"

[2] The disparagement, in general terms, of the quality of low-priced drugs is not, of course, limited to detailmen. High officials of major firms and trade associations have used investigatory hearings as a forum for disparagement efforts; the present Committee has been exposed to an unusually vivid account of the alleged shortcomings of so-called "copiers" and "counterfeiters", and at unusual length. But such efforts are probably most effective as between detailmen and individual physicians over a long period of time. The following instances are illustrative of the uses of disparagement:

(1) Dr. Solomon Garb testified before the Kefauver Subcommittee: "Although our students had been told by their teachers that generic names were preferable to brand names, in the first year of the project, a single session with a detailman apparently convinced about half the students that brand name prescriptions were better...In essence, they pointed out that products made by an unknown manufacturer may be impure, or of erratic potency..." (4m)

(2) Disparagement may be directed at one particular drug. Dr. Howe of this Committee stated that a detailman criticized the efficacy of a rival brand of penicillin relative to that of his own firm after having searched drug store prescription records to ascertain which brands Dr. Howe had prescribed. (7m)

If the physician can be induced to suspect the quality of all low-priced drugs, then the potential price competition which could develop in areas where drugs are unpatented is largely nullified. Not completely nullified, fortunately, since there are some areas in the drug market where better-informed purchasing agents buy from qualified sellers on a price basis. But the individual physician is vulnerable to having his confidence in low-priced drugs undermined by disparagement since he is not in a position personally to evaluate the quality of the drugs he prescribes. As in any case where the buyer lacks full information on the nature of the product at the time of purchase, selling efforts take on some of the aspects of a "confidence game" where the buyer is induced to take the seller's word that not only is his product satisfactory but far superior to those of his rivals. Naturally the past reputation of his firm is portrayed in a favorable light, while the unknown and hence allegedly dubious reputation of smaller sellers is hinted at. Since the technical details of producing safe and effective drugs are within the province of competence of both large and small sellers,[1] the "reputation"

---

[1] In an effort to misdirect attention from generic names to brand names, the National Pharmaceutical Council in the United States published an educational booklet entitled "Twenty-Four Reasons why Prescription Brand Names are Important to You". Dr. Walter Modell, Professor at Cornell University Medical College and chairman of the Formulary Committee of the New York Hospital, gave his critique of the book:

> "Everything in here is true. These are just a list, as I said, of truisms. Reliability does provide all of these things, but these are not secrets. Anyone who is conscientious can do this."

Contending that all the alleged superiorities of brand name drugs made by the larger firms over generic drugs sold by smaller firms were specious, Dr. Modell insisted that the capabilities claimed to be monopolized by brand name firms were in fact the common property not only of small firms as well as large, but even of well-trained individual pharmacists who might extemporaneously compound drugs. (4n).

to which the saleman refers is determined almost wholly by the impack of massive and long-term advertising and other sales promotion devices. Hence a low price in itself becomes associated in the physician's mind with low quality. Only an agency which is able to determine for itself the quality of the products of both high and low price sellers will become immune to disparagement efforts. This is the most important reason for insisting upon providing the Food and Drug Directorate with sufficient authority and funds to guarantee the quality of all drugs offered on the Canadian market.

Actually, there is very little reason to suppose that low price means low quality. Both brand and generic name drugs must meet official standards listed in authoritative compendia. Experts have testified that there is no therapeutic gain realized by producing to purity standards exceeding official standards. (4n). The products produced by brand and generic name manufacturers are subject to the same inspection procedures; each will be held to the same standards. A small producer is even more strongly motivated than a large producer to conform to requirements, since the impact of a given fine for violation will be much more serious to his finances. This danger should outweigh any financial advantages which might be realized by economizing on the content of the active ingredient or on quality control. Official standards will specify a certain range of tolerated fluctuation about stated potency, for example, 90 to 110 per cent. But the cost of the active ingredient in a given drug is typically only a small part of total cost, and the cost saved by orienting the production process to produce an average content of 90 per cent rather than 100 per cent stated label potency would only save a fraction of this small part of total cost; furthermore it would result in the production of a substantial number of violative drugs and would expose the firm to fines and other sanctions by the inspectors--which would clearly not justify the risk.

Nor is quality control so costly as to be a monopoly of the larger firms. One of the few differences in the defenses adopted by drug

firms in the Canadian and United States investigations is the relatively greater emphasis on quality control expressed at the Canadian hearings. Efforts to justify high drug prices by reference to the magnitude of research budgets are, to say the very least, overstated; but efforts to justify prices in terms of the cost of quality control border on the ludicrous. Admitting the difficulty of isolating quality control costs as distinct from general manufacturing costs (which raises the question as to why the firms are so interested in the distinction), the estimates of quality control costs as a per cent of the sales dollar in 1960 in Canada are given in the Green Book as ranging from 1.21 per cent to 4.2 per cent for samples of from 22 to 35 of the largest firms. (2j). For smaller, lower-priced firms the ratio would probably be somewhat higher, but would still not be a controlling factor in costs. Neither small nor large firms can dispense with quality control; the production of marketable products requires it. Yet large firms discuss their quality control programs in such a way as to suggest that (1) as a philanthropic gesture they are gratuitously undertaking to provide the public with quality-controlled drugs, while smaller firms need not do so; and (2) that quality control in the drug industry is different and superior in kind from quality control in other industries. Neither suggestion is valid. Once a firm decides to produce drugs and sell them in an inspected market, it becomes impossible to do without some means of quality control. During the fermentation of a batch of ingredients designed to produce antibiotics, constant quality control is a necessity, not in the interests of pampering the eventual drug buyer by over-insuring quality *per se*, but for the purpose of avoiding contamination and hence sustaining a loss on the entirety of the work in process. Furthermore, quality control is of more than passing importance in other industries as well. In the automobile industry, for example, the quality of moving parts produced subject to very close tolerances, such as crankshafts, is a matter of not inconsiderable importance to car buyers. Yet car makers do not feel compelled to justify

the prices of automobiles by constant reference to quality control costs; these costs are after all incurred in carrying out routine and mechanical processes which are largely taken for granted. That drug firms publicly celebrate their inability to take processes for granted may--or may not--be cause for reassurance.

Moreover, most small firms buy drugs in bulk form from large firms, and merely tablet and package the finished dosage forms. They may even simply package bulk tablets, or even merely put their label on unlabelled bottles of finished dosage forms. Pejorative comments by larger firms may often imply some criticism of their own bulk drugs or finished dosage forms, as sold by smaller firms.

Possibly the best argument why quality differences might be expected to exist between high priced and low priced drugs is the contention that the Food and Drug Directorate is underfinanced, understaffed, and unable to make sufficient inspections. It is in the interest of the higher-priced producers to overstate this case. It is also true that a shortage of inspectors implies insufficient inspection of the facilities and products of large as well as small producers. Hence the remedy to the problem of insufficient inspections is not to prohibit or discourage by propagandistic activities the sales of drugs at lower prices. This would merely increase the monopoly power of large firms in those few areas of the market in which price competition exists, and would accordingly increase that part of the profits of the large firms which constitutes monopoly returns. Furthermore, it would not remedy the insufficient scale of inspection of large firms.

The obvious remedy is to provide fully adequate inspection. It has been objected that this would cost too much. But the benefits are certain greatly to exceed any costs. I do not have available any data which would allow a cost-benefit analysis in the Canadian context, but the statistics relating to the United States indicate clearly the order of magnitude of prospective costs and benefits. In 1958, the net profits before taxes earned by the 22 largest drug firms in the United

States amounted to $562 million. Food and Drug Administration Commissioner Larrick estimated that it would take a budget increase of $3,418,000 to obtain adequate inspection. A reduction in drug prices sufficient to cut drug firm revenues by $7.121 million would of course cut before-tax profits by $7.121 million. With the tax rate at 52% at that time, this reduction in pre-tax profits would have cut tax receipts by $3.705 million. The net gain to the country would therefore have been the $7.121 million saved by the drug buyers, minus the $3.703 million in reduced tax receipts, or the needed $3.418 million. Thus, if adequate drug inspection could establish confidence in lower priced drugs to the degree that the resulting competition would lower major drug firm prices by enough to cut total profits by as little as 1.27 per cent before taxes (if total profits are about 20% of gross receipts, prices might be cut by as little as ¼ of one per cent), the savings realized would pay for the expanded enforcement program. In addition, the substantial benefits obtained from the elimination of inferior drugs would have to be included in appraising the value of an expanded enforcement program.

Further drawbacks of the practices of massive advertising and brand-name prescribing include the consequences of such additional confusing of market information which results in not only obscuring the low-priced drug alternatives from the physician's view, but also in making it more difficult for the physician to identify the full range of substitute medications available for treating a given disorder. Suitably devised (and advertised) generic names might provide some guide in identifying pharmacologically related compounds; heavily advertised brand names suggest no such relationship, and the limiting case of confusion would occur when the physician may serially prescribe two or more brand name versions of an identical substance because the brand-name disguise has deceived the physician as to the identical character of the drugs. (on economic grounds alone, I regard contentions that different firm's preparations of chemically identical compounds are therapeutically significantly different as overstated and without real merit. If there

are different ways in which to capsule form, for example, of a particular drug can be prepared which significantly affect the therapeutic potential of the drug in treating certain disorders, it is not to be expected that firm A will produce a dosage form which is adapted to treating disorder X, firm B will produce one which is adapted to disorder Y, and so on. Instead, to the extent that there are significant market potentials in treating each of these disorders, or forms of a given disorder, each firm will tend to produce all of the varieties of the dosage form preparation. Differences may exist, but they are likely to represent secondary or marginal product differentiations.)

That aspect of sales promotion which takes the form of the distribution of free samples benefits not only from having rival brands of the same drug being given different brand names, but also different colors and shapes. It is certainly enterprising of generic producers to duplicate the forms and colors of brand name drugs; other things being equal, it would increase the degree to which price competition might develop between different sellers of the same drug. While such duplicates might plausibly be called "copies", it is rather an unscrupulous use of language to call them "counterfeits" unless they illegally reproduce another firm's trademark or other uniquely distinguishing imprint on the dosage form itself.[1]

---

[1] In this regard, it is rather amusing to observe that two types of public relations activities of major drug firms work rather at cross-purposes, and that this contradiction has apparently escaped detection by the co-ordinators of public relations strategies. On the one hand, disparagement--usually in general terms--is not limited to detailmen, but is engaged in by drug industry spokesmen from the vantage point of a variety of forums, and is directed against the quality of generic products. On the other hand, in order to create a sympathetic image of the large company as being persecuted by illegal competition, the danger of drug counterfeiting is repeatedly urged upon the public, and possibly the danger is exaggerated. Perhaps the intention is to confuse in the popular mind the image of the small firm as relatively unknown competitor, and as clandestine counterfeiter. Nevertheless, if one takes the trouble to pursue the implications of such pronouncements, it follows that one is safer to insist on generic drugs than upon brand name equivalents. Since counterfeiters would find it more profitable to produce ten-dollar bills than copper cents, it follows that the high-priced drugs of major firms would naturally be preferred subjects of counterfeiting, instead of the low priced generic drugs.

2. Costs Incurred by Distributors

In relation to profits and sales promotion outlays, distribution costs do not appear to be extremely high: the PMAC submission assigns a cost of 4.0 per cent of the sales dollar to distributing and warehousing costs. Naturally, not all of the distribution costs are included in this figure; only those distribution costs incurred by manufacturers are covered. Apparently the smaller firms rely more heavily upon wholesalers than the larger firms; nevertheless, no firm is said to rely entirely on its own facilities for all distribution of its products. Hence the 4.0 per cent of the manufacturer's sales dollar covers an unknown percentage of total industry distribution costs.

It is asserted that the large areal extent and low density of population in Canada necessarily means high distribution costs. While this is undoubtedly a factor, it is noteworthy that no attempts have been made by drug firms to make quantitative estimates of the influence of this factor on distribution costs. In the same general sense it is also asserted that the bilingual character of Canada tends to increase marketing costs. Again, while there is some point to this assertion, one is left in doubt as to the actual cost impact of this factor. Clearly, the mere facts that a country is large, thinly populated, and bilingual does not justify any and all levels whatsoever of marketing and distribution costs. It may justify some level of additional costs over, say, comparable costs in the United States, but no evidence beyond mere assertion has been provided.

a. Wholesale Distribution.

Distribution costs incurred by wholesalers cannot be estimated from available data, but it appears that net operating profits of drug wholesalers are not high, so that distribution costs would be closely related to the wholesaler's total revenues less cost of goods sold. For 1957, for example, drug wholesalers made a net profit of 1.45 per cent on sales, and ranked seventh among eleven types of wholesalers in regard to height of profit ratio on sales. While the profit ratio tells us nothing in the absence of data on turnover, the relatively low ranking compared with other retailers is probably

significant. (2k). Wholesalers spent only 0.14 per cent of total sales in advertising, and again ranked seventh of the eleven types of wholesalers in this regard. Little interest has been expressed in the efficiency of the performance of the drug wholesaler, and this may indicate reasonable satisfaction with the performance provided. In an efficiently competitive drug industry, the wholesaler would receive an operating margin which would reflect the market value of the distribution services rendered. At present, for those drugs sold through wholesalers, the share of the wholesaler in the drug buyer's dollar would appear to be about eight and one-third per cent. Assuming that the suggested list price is $1.00, the price to the druggist will be 60 cents, and the price paid by the wholesaler will be 50 cents. But the prescription surveys of the Canadian Pharmaceutical Association show that the average prescription price represents a doubling of the druggist's cost, hence the prescription will be dispensed for $1.20, and only 10 cents of this is kept by the wholesaler.

Of all the businesses engaged in the drug industry, the wholesaler operates in the most competitive market, relatively speaking. Drug manufacturers have their markets protected by patents, trademarks, tariffs and dumping duties, sales promotion practices, fewness of numbers and large average size. Druggists have a protected market because of the institution of brand-name prescribing and other prescription regulations which put the consumer at a unique disadvantage, plus the advantages associated with being a closed profession regulated by semi-autonomous professional associations which may be able to limit entry. But the wholesaler has no comparably strong bargaining position. There are relatively many relatively small wholesalers, and no real barriers to entry. If unsatisfied with the performance of wholesalers, drug manufacturers can integrate forward and sell directly to retailers. Similarly, groups of retailers, or even larger individual retailers, can integrate backward, as it were, and buy directly from the manufacturers. Hence the wholesaler must provide suitable

services, reasonably priced, or find himself out of business. This is not to say that there cannot be inefficiencies in drug wholesaling, but one would expect to find fewer at this stage of the industry than at any other.

b. Retail Distribution

Efficient competition in the retail distribution of prescription drugs would require price competition among sellers. Pharmacies are inherently rather small-scale in nature, and although reasonably numerous in urban areas, monopoly problems might arise in isolated areas unless there are alternative sources of supply, such as might be provided by mail-order service. Capital requirements pose no major barrier to entry, but no other barriers should be present if performance is to be competitive. All sellers should act strictly independently in regard to pricing policies; no formal or informal arrangements which would facilitate uniformity of action on price policies should exist. No need for keeping excessive inventories should be present. Prescriptions should be written in such a way as to facilitate the ability of drug buyers to stimulate price competition among pharmacists. The requirement that prescriptions be written generically would serve both purposes. Public inspection of drug products should be adequate to insure the quality of all drugs on the market. No such practices as "coding" prescriptions should exist. There should be no barriers to the dissemination among buyers of information on the prescription drug prices of individual pharmacies. Buyers must be free to seek out the lowest-price seller, both for the original dispensing of a prescription, and for refills. Under these circumstances, prices would be reduced, inventory costs could be cut, the average quality of drugs improved, the efficiency of retail distribution of drugs increased, and the disadvantage under which the drug buyer presently labors could be greatly lessened.

Under the existing circumstances, the market disadvantage of the drug buyer is extreme. The physician acts as the purchasing agent for

the patient, but does not pay for the drug. Hence the physician is not motivated to prescribe the least costly preparation[1] (or even to become aware of price) except to the extent that he may prudently calculate that the lower the drug bill, the more certain the expeditious payment of his own fees. (It is even possible that the doctors who prescribe the more expensive drugs may be accorded the greater prestige.) The patient who is burdened with a high-priced brand name prescription has no alternative at present but to pay the full price, or fail to purchase the drug, and thus be deprived of the benefit of the medical advice for which he is charged. To reduce the impact of possible ignorance of or indifference to drug prices on the part of the physician, two approaches might be pursued. Firstly, dissemination of information on the typical cost of a course of treatment with different medications. This might be a regular feature in articles evaluating the relative advantages of different drugs which would appear in independent newsletters. Legislation might also be passed to require that all drug advertisements prominently feature suggested retail prices, but there are disadvantages since it would not be legal to require that these prices be actually charged, it might facilitate price stabilization, and it might induce sellers to quote relatively higher prices than they expected that the average retailer might charge. On the other hand, some guide to prices is perhaps better than none; and the physician who is sensitive to the economic health of his patients could perhaps become aware of the relationship between suggested list prices and actual patient charges at various pharmacies, and convey to his patients information on the relative

---

[1] Dr. J. W. Reid, a medical practitioner in Halifax, made the following statements during the Restrictive Trade Practices Commission hearings:

> "...if I knew what the cost of a drug was, I might not prescribe it...".

But then qualified his answer:

> "I must say that we do become familiar with the cost of a drug as time goes on, and it does cause us a little thought, perhaps, but it does not interfere with prescribing." (1b).

markups or "professional fees" of different pharmacies.[1] Secondly, direct action should also be taken to institute price competition and thus reduce the level of all drug prices, so that even non-price-conscious physicians would not run the risk of imposing economic burdens on patients by prescribing in ignorance of relative prices. Such actions would include eliminating all the various barriers which make it difficult for small, lower priced producers to compete in the market with large and higher priced sellers. These measures are discussed at length in Chapter III of this presentation.

Optimal economic efficiency in the dispensing of drugs would require that the mark-ups which the retailer places on drugs be determined by price competition among sellers.[2] Hence the mark-up should be at the minimum rate above cost which is consistent with the retailer's cost of distribution, including a competitively determined rate of return on an appropriate level of investment in inventories and other facilities. In general, the larger the volume of business of an individual seller, the smaller his investment per dollar of annual sales, and the lower the rate of necessary markup over cost. The druggist who lowers prices beneath the levels of his rivals may find that the resulting increase

---

1 As a college professor, I am concerned in the only other market I know of which bears any resemblance to prescription drugs. Professors may be said to "prescribe" textbooks for their students. But students have certain alternatives not open to drug buyers, such as textbook sharing or the second-hand market. I am personally quite conscious of the cost of textbooks to students and try to minimize such costs by selecting lower-cost books, minimizing the number of required texts, and using paperbacks where possible. In one instance I succeeded in having the University purchase a number of copies of a reading book which was placed on reserve in the library for student use on the premises. At that time I was employed by one of the wealthiest universities in the United States in terms of endowment per student, and hence considered this arrangement not inappropriate.

2 Mr. Turnbull of the Canadian Pharmaceutical Association made the following statement to this Committee:

> "I would respectfully suggest that each individual knows the value of his own service and places a monetary fee on that" (7kk).

In a truly competitive market, however, it is the market and not the seller himself which places an equilibrium price on the services rendered by the druggist.

in business volume reduces costs so as to more than justify the price reduction. If genuine competition exists, the method by which the markup is arrived at will be relatively unimportant, since competition will require that the amount of the markup be very nearly equal among competing sellers. Under imperfectly competitive circumstances, however, there are advantages in having a "professional fee" added to drug cost, rather than having the cost subject to a flat rate markup. If generic prescriptions are received, the flat rate markup induces the substitution of brand name equivalents for the specified generic drug, since the profit margin in applying the same markup to the higher cost good is greater. But if a "professional fee" is added to each order, regardless of the cost of the drug to the retailer, this bias disappears.

As to the actual status of price competition among retail druggists in Canada, it seems to be distinguished by its almost complete absence. The very last paragraph in the Green Book concludes:

> "It is, however, clear that there is virtually no price competition in the sale of ethical drug products at the retail level. Price competition among suppliers is the factor which is normally relied upon to control the prices charged by suppliers and to ensure that consumers can purchase at reasonable prices. In the case of ethical drugs, no such control exists." (2m).

Hence monopoly power at the manufacturing level is accompanied by lack of competition at the retail level to put the drug buyer at a double disadvantage. Structurally, however, the constitution of the retail market would seem to be much more conducive to price competition than that of the drug manufacturers. There are a large number of small pharmacies, and there are no purely economic barriers to entry such as would be posed by large capital investment requirements. What barriers do exist are apparently more in the nature of legal and, as it were, quasi-guild restrictions. In the last dozen or so years I have been largely engaged in studies of industrial organization and the public regulation of industry so as to restrain monopoly power and promote competition. As far as the United States is concerned, my attention has been continually drawn to certain of the activities of organizations of druggists which relate to eliminating, or at least minimizing the vigor of price competition on drug store products, including of course

prescription items. In spite of myself, I have been compelled to admire the persistence and single-mindedness of these groups in pursuing the goal of abolishing price competition on drug store sales. Other organizations of numerous small sellers have been less active and militant--such as those representing variety store, auto supply stores, department stores, and even retail food sellers. In fact, the organized druggists have carried much of the load for the other retailers; the role of the National Association of Retail Druggists in securing the passage of state and national so-called "fair trade" laws in the United States in the 1930's is notorious.[1]

Naturally, no seller enjoys price competition. But why druggists in the United States should be so much more active and successful in opposing it, when many other groups had as much or more to lose by it, and yet did not present the same highly organized united front against it, has persistently puzzled me. If there is an answer, I suspect that it is related to the attitudes cultivated among pharmacists by membership in their professional associations, particularly the notion that it is "unethical" to refer in any way to prices charged for prescription drugs.[2]

---

[1] This can readily be verified by reference to any good textbook on industrial organization. For example: "But the gadfly of all the organized business-interest groups is commonly recognized as the National Association of Retail Druggists; the NARD has had more to do with the success of the fair trade movement than any other single organization." (17) "Moreover, well-organized dealers like druggists can use fair trade to increase their margins. Acting together using or threatening to use black lists or white lists, promising to push some products or threatening to put them under the counter, they can persuade manufacturers to set fair trade prices at levels which will increase the retain markup. The National Association of Retail Druggists have used fair trade as a weapon in its long campaign to assure its members of a markup of at least 50 per cent." (18).

[2] In 1959, a druggist in Toronto had displayed a sign which advertised prescriptions at ten per cent off. Four local druggists wrote the Ontario College of Pharmacy as follows:

> "We, the undersigned, feel very strongly about the ethics of this pharmacist and would like to have him remove the notorious streamer at once. We would like to have him follow the Code of Ethics as enunciated in the Ontario Pharmacy Act or cease to carry on in this disreputable conduct. We feel that this method of going business is not desirable and ask that the infringement committee convene at once to handle this situation." (2n).

Clearly, the lack of price competition among pharmacists is a major factor in the high cost of drugs, and it must be faced by this Committee. I do not hesitate to admit that while I admired the late Senator Kefauver for his effective challenge to drug industry abuses in the United States, I admire the Canadian investigations still more for their explicit consideration of the possible role of the druggist in influencing the high level of drug prices in Canada. It is clear that the investigators in the United States did not wish to provoke the opposition of the highly organized retail druggists--at least, not at the same time they were fighting the lobbying efforts of the drug makers. But the Report of the Restrictive Trade Practices Commission is quite explicit as to the fact of lack of price competition among druggists. (1c, 2o).

This lack of competition appears to be traditional, if for no other reason than the severe disadvantages the drug buyer suffers in the market. The father of modern economics, Adam Smith, noted in The Wealth of Nations, back in 1776, that "Apothecary's profit is become a bye-word, denoting something uncommonly extravagant." (19). And at that time, when the professions of physician and pharmacist had not yet been generally separated, the control of the prescriber-compounder-dispenser over the patient must have approached the absolute. Even when physicians and pharmacists became separate groups, the patient was still largely at the mercy of the pharmacist, who generally compounded the medicinals which he sold. In North America it was not until the early years of the nineteenth century that certain apothecary shops began to specialize in producing larger quantities of medicinals for sales to other apothecaries. This might have given rise to the possibility of some price competition between resellers of purchased medicinals, but there is no evidence of any sort of price competition until the advent of the "cut-rate" drug store in the 1880's, and even then the price competition referred to other drug store goods than prescriptions. (20). Hence, although the pharmacist might realize high profit margine on prescriptions during this era, these margins reflected not so much his inventory investment as a merchant, as it did his compounding skills and services as a professional

man. (The Adam Smith quotation above is followed by a section in which high unit profits are related among other things to the skills in practice of the apothecary.) Although the ratio of prescriptions compounded to prescriptions merely dispensed probably continued to decline slowly throughout the last hundred years or so, as the manufacture of drugs became increasingly widespread, it is only within the last decade or so that the ratio has become insignificantly low...five per cent or less (1d). The pharmacist's function has changed from that of active compounding to passive merchandising; many of his skills have become largely obsolete as a result of the "revolution" in the drug industry.

In less custom-oriented professions, or in a more competitive environment, the obsolescence of the pharmacist's unique function would have reduced his market importance and his remuneration. This had not happened in North America. But before enlarging upon the present situation and its implications, recall that a monopolist does not necessarily make monopoly profits. Nor does a group which wishes to legislate away or otherwise rule out price competition necessarily enjoy the hoped-for benefits of high earnings. It may be possible to maximize net profit per unit sold, but unless completely effective ways to prevent new entry into the market can be found, new firms will be attracted by the high unit profits which are protected by custom, law, or agreement. As new firms enter the market, average sales per firm decline, and an equilibrium may be reached where so many new sellers have been attracted into the industry that the decline in turnover has reduced profits on investment to no more than competitive levels. Only at this point will new entry cease.

In the United States, where resale price maintenance laws were enacted under the euphemism of "fair trade," the results have been largely disappointing to the sponsors, not only because of adverse decisions by some state courts, but because of an inability of druggists and others to limit entry and prevent turnover from declining. (21). This situation compels misallocation of resources since high unit margins mean

increased prices and reduced sales, but the low turnover per store means that each dealer typically has excess capacity; hence total investment is excessive relative to the amount of business being done. Lower prices would increase production and consumption, eliminate excess capacity, and result in rates of return on investment which are no smaller than previously earned. In the United States, drug stores, like other fair traders, have suffered from increased entry, although they have some advantage over other sellers in that state boards of pharmacy may be able to some extent to limit the number of pharmacists and hence the number of potential entrants into the market. Canada has wisely achieved the abolition of resale price maintenance, and one would expect price competition except perhaps in a few of the larger metropolitan areas. On the contrary, it appears that pharmacists are able to levy even higher charges for their services than can their counterparts in the United States. The conventional markup in both countries is 66 2/3 per cent over invoice cost, but the superimposition of a "professional fee" in Canada increases the retailer's unit margin. The imposition of this surcharge for higher-priced prescriptions, where imposed, is persuasive evidence of the ineffectiveness of price competition.

If this situation prevails even in the absence of resale price maintenance, the problem is deep-seated and the solution at best is likely to be a very long run matter. Education might help in developing a more enlightened attitude on the part of pharmacy schools, students, and control boards, but the basic problem is one of injecting price competition into drug retailing. Efforts to educate pharmacy control boards to the idea that it is unethical, not ethical, to discourage price competition and hence overcharge the sick, may or may not be successful. To the limited extent that such lower-cost outlets as hospitals and public agencies can be substituted for traditional outlets, the problem will be alleviated. However, a more satisfactory solution must await the adoption of the maximum practical liberalization

of the traditional restrictions limiting entry into drug retailing. This liberalization should be such as to constitute recognition that the traditional pharmacist's distinctive functions are being altered away from professional competence in compounding and toward skills in merchandising. This, more than anything else, would probably bring about new entry into the market by those who are not traditionally opposed to price competition. In many lines of trade, sellers were inefficient and distribution methods stagnant and unprogressive until competition developed from such sources as supermarkets and mail-order houses. Drug "supermarkets" are by their nature more suited to large urban centers, but the encouragement of mail-order pharmacy, where feasible, would do much to spur competition in more thinly settled areas where druggists may have local monopolies. (Needless to say, the obstacles in the way of achieving such reforms are formidable, but hopefully not prohibitive.)

B. Factors Influencing Demand for Prescription Drugs

It is the nature of demand for prescription drugs which makes the industry an inappropriate vehicle for the unregulated exercise of market power by sellers. Instead, the industry is regarded in every nation as a candidate for some degree of regulation in the public interest. Different shades of emphasis, however, are placed on regulation to insure the safety, quality, and reasonableness of price for the products sold. Basic to an understanding of the economics of the drug industry is the fact that prices have virtually no relationship to costs. This is a point which deserves considerable emphasis. It is of course contrary to the industry position.

It is broadly true to say that in any industry price is determined by the relationship of supply to demand. In a purely competitive market, price is determined by the relationship between the supply price of a good, defined as the cost of producing a given volume of output (where costs include a competitive rate of return on necessary investment) and the demand price which the market is willing to pay in order to purchase a given volume of output. As long as the determinants

of supply and demand are substantially independent of each other, there is no circularity involved. Supply price depends upon properly defined production costs, and the demand price depends upon the consumer's need for a product and upon his income level. The relatively small number of prospective consumers who are both wealthy and needy will constitute the highest demand-price segment of the total market demand, but this will typically account for only a small part of total demand in most industries. In order to market higher quantities, prices must be lowered, since the more numerous group of potential buyers have more moderate incomes and/or more moderate needs or desires for the product. Only at very low prices will those with low incomes and/or lesser degrees of interest in the product be actual purchasers in the market.

On the supply side, if the expected price is very low, only a small output will be forthcoming, since only the most efficient producers can make and sell goods profitably at a low supply price. As the expected price to be received by sellers increases, higher cost (less efficient, less favorably situated, or otherwise less advantageously constituted) producers will enter the market. Hence, in a competitive market, the demand price which the consumer[1] has to pay will continually decrease with increases in the rate of output and sales, while the supply price at which the newly-entering firm can profitably sell continually increases with increases in the rate of output and sales. Equilibrium is reached at that level of output where supply price is equal to demand price. In a competitive market of this type, the price is thus determined by an equality between (1) the demand price of the consumer who, while actually in the market, is least anxious to buy; and (2) the supply price of the firm which is least able to earn profits after covering its total costs, which include an allowance for the competitive

---

[1] To be precise, the crucial demand price as output increases is the price at which the least interested consumer in the market at that level of output is just indifferent between buying the product and not buying it. To sell that rate of output, price has to decline to the point where the least interested buyer will purchase the last unit of output produced.

rate of return on capital invested. Hence the market price reflects, at the same time, what the good is worth to the buyer with least urgent wants, and what it costs the highest cost producer actually operating to make it. Under these circumstances, the buyer whose demands are urgent and whose income is high gets a great bargain, and sellers whose costs are very low (who are most efficient, for a variety of reasons) will make substantial profits. This system is economically optimally efficient in that the industry produces a given output at the lowest possible total cost. Why does the consumer with the most urgent demand pay no more than the consumer with the least urgent demand? Because the good is being sold in a purely competitive market; hence if there were any attempt to charge richer buyers higher prices and poorer buyers lower prices, there would be no obstacle to the poorer buyers reselling at only slightly higher prices to richer buyers. Arbitrage would soon establish a common equilibrium price. Only if there are barriers to such resale would richer buyers be compelled to pay higher prices. Such barriers are of course incompatible with a purely competitive market, but they do exist in other markets--for example, the market for medical services, where an indigent charity patient cannot resell his brain surgery to a wealthy patient. Where such barriers exist, different buyers may pay different prices for the same goods or services, even where the cost of supplying all buyers is the same. This amounts to price discrimination in the economic sense, and it results in an inefficient allocation of resources in that a given level of output may be sold, in the limiting case, at an absolute maximum total cost to buyers, the difference in receipts between the purely competitive market and the market with perfect price discrimination being equal to the monopoly profits realized by the seller. Such price discrimination seems to be practiced in the drug industry between, for example, antibiotics in human pharmaceuticals and in livestock feed supplements.

Another question arises. Why does the market have room for both efficient and inefficient firms? Why do not the efficient firms drive the inefficient out of business? Simply because the total market demand at the equilibrium price level happens to be great to be supplied

entirely by the most efficient firms. Hence the excess of total demand over the amounts which can be supplied by the lower-cost firms has to be supplied by firms with increasingly higher costs of production. This implies that the efficient scale of production for a lower-cost firm is small relative to the entire market. This is in fact one of the previously mentioned structural requirements for pure competition--that there be numerous relatively small firms. If economies of large scale production existed, such that one or a very few efficient firms could supply the entirety of market demand, then pure competition becomes impossible and the market devolves into a situation characterized, at one extreme, by monopoly, or more probably into a market conferring varying degrees of monopoly power on the sellers individually.

In the case of monopoly by a single producer, the structure of market demand is still the same as in pure competition, but now it is surveyed by a hypothetical single monopolist who regards it as his private preserve, to be cultivated without the necessity of sharing it with other sellers. Such might be the position of a patent monopolist producing a unique drug. The seller is now in a position to set the price and output jointly in such a way as to maximize his profits. The resulting price and output will depend largely upon the sensitivity of demand to the price level--the so-called elasticity of demand. If demand is very insensitive to the level of prices (very inelastic), prices will be very high and output relatively low. If demand is highly sensitive to price levels (highly elastic), price will be lower and output higher. Typically the monopolist will have a supply position determined by economies of large scale production, such that average production costs decline until output rates become high relative to total market demand. This is not necessarily the case, however, and if the optimum size of plant is small relative to the profit-maximizing output, as seems to be the case in the drug industry, the firm might build several moderate sized plants (or employ a large number of standard sized process facilities, like the fermentation vats used in antibiotics) or perhaps license his patented process to others to produce and/or sell,

maximizing his profits in terms of the royalty and other licensing conditions which he imposes.

In the case like this, and assuming the existence of the very inelastic demand which is typical of prescription drugs, while the market price of the least urgently necessitous individual, this price will nonetheless be absolutely quite high in view of the urgency of demand on the part of all buyers of drugs. What is in some ways even more important, the price will be greatly in excess of the average cost of production of the product, allowing an excessive profit margin to the seller. Resources are misallocated to the extent that prices are high, output is low, excess capacity therefore is likely to exist, and the profit received by the seller is much more than the minimum level necessary to elicit the supply of his productive services--in other words, greatly in excess of the supply price of his output in a competitive market.

Monopolists are notorious for charging "what the traffic will bear," which is just another way of saying that the full demand price is exacted. Naturally, as long as the act of purchase is voluntary, no one will literally pay more than what a good or service is ultimately worth to him. But under either pure competition or pure monopoly, or any other market structure where there is no price discrimination, market price paid by all is equal only to the full demand price paid by that buyer who, while actually making a purchase, is the least interested buyer for that good presently in the market. Under pure competition, output will generally be so great that the price paid is relatively low; under monopolistic circumstances, output will be restricted and the price paid will be relatively higher. Similarly, the chances of the typical buyer getting a large "free" or "surplus" increment of "use value" over and above the amount he paid for the purchase are much greater under pure competition than under monopoly. The chief difference, however, is the relationship between price and cost of production. Under pure competition, the price paid is equal to the full cost of production (including a competitive rate of return on investment) of the last producer whose output is required to satisfy

total market demand--hence the demand price is equal to the competitive supply cost. But under monopolistic circumstances, the price is equal to what the traffic will bear, and is often far above production cost.

Hence when the drug makers argue before public bodies like the present committee that the consumer is paying no more than the good is worth to him, the only appropriate response is: of course not! In the absence of compulsion, he simply could not be induced to pay more for anything than it is worth to him, no matter how great the monopoly power of the seller. The real question is: what is the relationship of price to cost of production? The greater the relative gap between price and cost of production, the less competitive, more monopolistic, and more inefficient in the allocation of resources, the market will be.

As mentioned above, in analyzing the demand for drugs, it must be kept in mind that income levels are of co-ordinate importance with physical needs. In any marketplace, money talks, and sellers mean business, not chivalry--which is as it should be at this stage, if resources are to be properly allocated. But this argument is compelling only where markets are competitive and demand is strictly voluntary. While demand for a drug is price-inelastic to the extent that the need for it is urgent, demand relative to the ability to pay, or the income-elasticity of demand, is often more important than price elasticity. This is especially true for low-income patients, and for those requiring constant medication for chronic disorders. It is well known that individuals with severe inflammatory diseases and low incomes sometimes do without food in order to buy drugs. (4p). Ideally, the total potential market for a drug or a group of related drugs is measured by the total need for medication on the part of all individuals afflicted by all the various disorders which are capable of being treated best by the drug or group of drugs. Economically, the total effective amounts demanded at the level of market price charged may fall short of total physical need in the case of individuals with low incomes and no access to public care. Equally importantly, effective demand may exceed ideal total physical need to the extent that individuals not suffering from those disorders for which the drug or

drugs are of use, may nevertheless be treated with them. For any given drug it then follows that the actual relevant market is comprised of the total effective demand for medication on the part of all individuals who can be induced to consult physicians, and who are afflicted by those disorders for which doctors may be inclined or persuaded to prescribe the particular drug. It is with the matter of persuading the physician to prescribe, of course, that sales promotion executives are constantly preoccupied.

Changes in the effective demand (i.e., prescriptions written and purchased as written) for individual drugs are brought about by direct mail advertising, medical journal advertising, the bestowing of free samples, the purchase of exhibit space at conventions, the financing of symposia, and the incessant insistence of detailmen. While advertising cannot manipulate the total incidence of disease, it can shift effective demand from one drug to another, within, or even among, differing drug groups. (In a sense, certain types of advertising can create demand. Articles planted in newspapers or magazines may mention the name of a drug which is alleged to be efficacious in treating a given condition, and thus make more people who suffer, or imagine that they suffer, from such conditions aware that drug therapy can be purchased.) Two of the greatest drawbacks of sales promotion in drugs stem from these characteristics of demand. First, physicians may be oversold on a drug because of intensive advertising, minimization of data on adverse reactions and maximizations of claims, such that it is prescribed entirely too widely, often for minor disorders where it can do no good, and may cause positive harm. Antibiotics are usually cited in this context. But other drugs may be overused and it is particularly serious when the drug is given for chronic, rather than acute, condition. Mr. Mark Nickerson, Professor at the University of Manitoba Medical School, estimated that the sales of adrenal steroids in Canada and the United States was about $250,000,000, and commented,

> "...personally I feel that I am being very liberal when I say that fifty million of that was needed." (1e).

Second, and closely related to the first drawback, is that patients themselves often insist on unnecessary drug administration. Dr. J. P.

Gemmell of the University of Manitoba Medical School commented on the seriousness of this phenomenon, concluding that:

> "I almost feel the public has transferred its belief in doctors to its belief in drugs." (1f).

This may have serious consequences for the medical profession. Dr. Walter Modell of Cornell University Medical School predicted that if an aimless proliferation of mediocre and possibly dangerous drugs continued to flood the market with adverse results on the quality of medical practice, then when the public lost its faith in drugs it would also lose its faith in doctors, and during the ensuing phase of "therapeutic nihilism" would desert allopathic physicians in favor of non-chemotherapeutic healers. (9g).

When markets are imperfectly competitive the question of income redistribution assumes a degree of importance perhaps co-ordinate with that of resource allocation. Under pure competition only the necessary costs of production are being financed by purchasers' funds, plus profits which go to producers in proportion to their efficiency, and can therefore be regarded as a direct reward for efficiency and an indecement for further efficiency. At least this puts funds in the hands of the most efficient producers who might be expected to invest these funds in the most productive channels. But where there is no discipline on the level of costs, and where monopoly profits are large in sum, income is being transferred from consumers to managers and stockholders. If managers make inefficient use of these funds, a levy is being exacted from consumers to subsidize inefficiency. And the sort of income redistribution which is incident to a transfer of income from consumers to stockholders depends chiefly upon the incomes of consumers; it can safely be assumed that the incomes of stockholders are on the average well above the median. If the good sold is an expensive luxury, the degree of income redistribution is perhaps not too pronounced. But if the good is a very expensive necessity, it is likely that the average income levels of buyers is comparable to that of the general population, and that the relative impact on the budget of such purchases becomes increasingly severe as income levels of buyer decline. Hence there may be an increase in the inequality of

the income distribution which is not compensated for in terms of allocating more investable funds into the hands of the more efficient firms.

Even in an efficiently competitive market, however, the incidence of the costs and benefits of privately financed individual health care would be characterized by "external economies" of the type which was discussed in connection with basic research. Let us contrast the cost and benefits from public health measures with those associated with private health care. The costs of the former are very largely by taxes. Here, the general tax paying public has, according to the incidence of taxation of the people, borne the cost of measures which benefit the entire public. The costs of the latter, if borne entirely by the afflicted individual, involve an external diseconomy to the individual, and an external economy to the society. A person who pays the costs of combatting his own illness has not only conferred a "negative benefit" upon himself in the form of the avoidance of further suffering, but has also benefitted society by eliminating the danger of its being exposed, perhaps, to contagion, and also by restoring his own productive services to the uses of society in co-operative production. When this argument is combined with the unexpected, involuntary, and uncertain impact of drug and other health care costs, it reinforces in a sense the case for private health insurance. But it may also be used to justify some undeterminable degree of public subsidy of the indigent through limited public health insurance programs. This is not to say that the monetary value of the excess of social benefits over private costs in the private health care sphere can be measured, and this total excess in dollar terms allocated to subsidizing insurance for the poor, but it does provide a basis for arguing that such activities bring public as well as private benefits. The use of the above perspective enables the point to be made more emphatically; to the extent that external economies result from private assumption of personal health care burdens, there are external diseconomies to the individual who seeks adequate care; but to the indigent person who hopes to get by with foregoing care, it is

paradoxically an external economy. If he endures a prolonged contagious illness and infects others, he has borne only part of the total social cost of his illness, the rest of which has been shared by the persons infected.

An illuminating contrast may be developed by comparing the relative effects on the distribution of income of (a) medical practioner fees, and (b) drug costs, if we assume (1) that these costs are covered by private health insurance, and (2) that these costs are borne entirely by the patient personally.

If the patient is covered by a comprehensive health insurance policy, the costs of both physician fee and drugs will be shared between the patient and all of the insured on the basis of premiums paid. Under ideally comprehensive insurance (including payments for incomes foregone, as well as costs incurred, through illness) the patient would pay no more per year whether sick or well, hence he would be truly insuring himself, paying a relatively small but certain charge in order to avoid the danger of an uncertain but possibly quite large expense. The costs of sickness would be borne by the insured individuals in proportion to the ratio between premiums paid and total incomes. The total incidence would probably be somewhat regressive, in that the premium would represent a larger share of a low income than a high income. But the regressivity would be milder than in the case where a poor but uninsured individual becomes sick and incurs medical expenses in excess of his premium if insured.

If the patient is not insured, however, the impact of medical fees and drug costs, for a representative cross-section of patients, will show a widely different incidence. Let us first consider the impact of physician fees on the income distribution of patients.

In the course of doing research on two papers regarding the economic determinants of the spatial distribution of physicians in the United States (22, 23) I came to no firm conclusion regarding the extent of the time-honored practice of the physician of "tempering the wind to the shorn lamb" by charging relatively lower fees to poor patients

and recouping them through relatively higher fees to affluent patients. My impression, however, is that it remains an appreciable factor in the United States, but I admit that I have no evidence for Canada and hence no basis for assuming that Canadian practices differ from, or resemble those in the United States. To the extent that doctors follow this practice, they do indeed exert a Robin Hood influence on the distribution of income, transferring the incidence of relative expenditures from the poor to the rich. What is often overlooked, however, is that the medical Robin Hood must of necessity confine his activities largely to the sick; hence it is as if this Robin Hood were robbing the hospitals of the wealthy in order to distribute his largess among the inmates of the hospitals of the poor. But illness can be a burden even on the wealthy, and this sort of redistribution of income, while it takes from the rich and gives to the poor, takes entirely from those of the wealthy who are least able to afford it. Presumably a modern day Robin Hood would still be solicitous of the hospitals of the poor, but he would be more likely to rob the country clubs.

If, however, the private individual must bear the burden of drug expenses, then the direction of the Robin Hood effect is reversed. The rich and the poor pay the same price, and while the physician presumably realizes no net gain from undercharging the poor and recouping from the rich, the drug firm makes monopoly profits from all classes of buyers, wealthy to indigent. (I have seen no statistics on the value of drugs given by drug firms to charities which would persuade me that this amount is other than insignificant. Free samples may be used to an undetermined degree as starter doses, such that by preventing the sale of a few capsules it is stimulating the sale of several times as many.) Hence income is drained away from those who might well be the relatively poorest members of each income class--from the poorest of the rich as well as the poorest of the poor--and into the hands of drug firm stockholders, the average member of which group should be well able to provide for himself, thanks in large measure to the phenomenal rise in drug stocks brought about by the miracle drug

revolution of the past twenty years.

These points are worth making, even at the expense of some repetition, because of the almost complete neglect of these issues, particularly by drug industry spokesmen. Even if there were no private health insurance, the drug buyer purchasing from a purely competitive drug industry would pay chiefly for the cost of producing the drugs he uses. From an imperfectly competitive industry, the buyer is financing not only the comparatively small level of drug production costs, but large outlays on marketing and large profits before and after taxes. He is also financing a small amount of research. Drug spokesmen have defended the price of drugs by reference to research costs thousands of times, but to the best of my knowledge have never once raised the question of the propriety of having these costs financed entirely by the sick. To the extent that such expenditures are wasteful, they should not be financed at all; but in proportion as they benefit the general public, the justification for financing them solely out of the funds of the currently ill becomes increasingly questionable, especially in view of the unequal incidence of illness between and among age and income groups. Admittedly, this over-simplifies the problem; furthermore, its identification is not tantamount to its solution. Nevertheless it is a real problem and is a serious one.

C. Market Price as Resulting from Interaction of Supply and Demand

What does the above description of the nature of supply and demand imply for the pricing policy of the firm? A purely monopolistic seller could set prices in such a way as to maximize profits, but since the price chosen depends upon an estimate of demand, it is possible that the monopolist may either underestimate or overestimate demand. When Lederle began in December 1948 to market the drug chlortetracycline (under the more euphonious name "Aureomycin") it was in a limited sense a monopolist since this drug had in respects a broader range of activity than penicillin, and hence was the first so-called "broad spectrum" antibiotic. It was originally priced in the

United States at $15 for a bottle of sixteen 250 milligram capsules, which at the traditional markup of 66 2/3 per cent would bring the price to the patient up to a handsome $25. Now, the introduction of this drug had been preceded by a very costly sales promotion campaign, including the distribution of a controversial $2 million in free samples. (Lederle disputes this sum and maintains that the amount was closer to $200 thousand. Perhaps the lower figure is the cost, and the higher figure the sales price, for the same amount of drugs.) One can only infer that Lederle fully intended to achieve mass market sales, and had certainly made careful price and cost calculations accordingly.

But Lederle must have miscalculated; the price of $15 must have been above the profit-maximizing level, for in February 1949 the price was reduced to $10. ($16.67 to the consumer.) In March 1949, Parke-Davis introduced a competitive broad spectrum antibiotic, chloramphenicol, the so-called "Chloromycetin." This qualified Lederle's monopoly of the broad spectrum market, since the two drugs were in many applications capable of being substituted. In a purely competitive market, chloramphenicol would have been priced in relation to its cost, probably at a level much closer to $1 than $10. And if there had been even a scintilla of price competition, Parke-Davis would have priced its drug at no more than, say, $9.95. Instead, it chose to match Lederle's price of $10 to the very cent.

However, the broad spectrum antibiotics do not stand by themselves as unique entities. Penicillin actually has a broad spectrum of activity itself, and it might have been more appropriate to term the other drugs "broader spectrum" antibiotics. When chlortetracycline first appeared on the market, 10 million units of penicillin in bulk cost $9.50. By early 1950, competitive reductions in its price had reduced the cost to $4.75--a drop of 50 per cent in one year. The reason for the decline in the price of penicillin is simply that it was not subject to patent monopoly control, and its production increased rapidly as many firms entered the market, the resulting increase in supply relative to demand causing prices to decline

correspondingly. By February 1950, Lederle and Parke-Davis both reduced their broad-spectrum prices by the same amount, from $10 to $8. This may have been in response to the price decline in penicillin; if so, had there not been an unpatented, competitively priced antibiotic, this price reduction might never have been made. At any rate, it is indicative of the oligopolistic practice of price leadership that both firms cut prices by the same amount and at the same time. Neither went to $7.95, for example.

In April of 1950, Pfizer entered the market with another broad spectrum contestant, oxytetracycline, which it priced at a 5 per cent differential with regard to the prices of the other drugs. But not five per cent below; no, five per cent above, at $8.40. Still, after Pfizer's entry, price competition may for once have developed. In May of 1950, Lederle and Parke-Davis cut prices from $8 to $6, Pfizer failing to match the price cut until November. By September of 1951, the price of 10 million units of penicillin had fallen still further, from $4.75 to $3.75, a decline of 21.1 per cent. Pfizer cut the price of oxytetracycline then from $6.00 to $5.10, a reduction of 15%. This time it was the other two firms who failed to match the price cut until November, 1951. Neither undercut Pfizer. Between November 1951 and August 1960, six nominally different broad spectrum antibiotics found their way to the market. Five of these were different brand names for the same substance, tetracycline. The sixth, demethylchlortetracycline, was a marginally different compound. Each seller predictably placed his product on the market at the identical price of $5.10, even though demethylchlortetracycline contained 150 milligrams of the active substance instead of 250. Finally, after almost nine years of identical prices, Pfizer reduced priced to $4.35, a 15 per cent cut. This move was widely interpreted as a bit of political strategy, since it came only one month before the industry was scheduled to testify before the Kefauver Subcommittee on its antibiotics pricing and other policies. During the nine-year period of price rigidity in the broad spectrum field, the price of penicillin had fallen by no less than 92 per cent--from $2.50 to $.21 for 10 million

units. It is reasonable to suppose that during this period the costs of producing broad spectrum antibiotics declined by approximately as much as the cost of penicillin, the production methods employed being largely similar. (5d). In fact, the costs of chloramphenicol probably declined by even more, since the patent holder discovered a way of making the drug synthetically. A comparison of the price decline of 90 per cent in penicillin during 1951-1960 with the rigid price level for broad spectrum antibiotics measures the effect of patent protection, restriction of entry, and lack of true price competition in the latter market.

Drug industry spokesmen assert that their pricing practices result in declining levels over a period of time, with very few increases. That this is the case supports the hypothesis that monopolistic, rather than competitive, pricing is the rule in drugs. The price of a new drug is initially set at the profit maximizing level, and this price is typically precisely matched by large firms producing patented therapeutic equivalents. Prices of patented drugs may decline when the prices of unpatented substitutes fall, or when producers not yoked by patent restrictions are allowed to compete in the market. But the fact that most drug prices have held constant, or even declined moderately in the face of rising cost trends is apparently a source of pride to drug firms. If anything, it merely indicates the degree to which their prices are insulated from competitive forces. A purely competitive firm would be compelled to raise its prices each time its costs increased, since its profit margins are always at minimum acceptable levels. That drug prices have held constant or have declined during a period of increasing costs suggests that while early profit levels may have been exorbitant, subsequent profits may have been merely excessive, and still later profits are certainly not below competitive levels, or else prices would have been increased.

Other examples of the inherently non-competitive nature of drug pricing can be given. When the first oral antidiabetic drug, tolbutamide, was introduced in the United States market, the price was set at the same level as that of insulin, despite the fact that it was

almost certainly much cheaper to produce tolbutamide than to obtain and process the animal pancreas from which insulin is extracted. (5e). Also, cost reductions have been achieved without any of the cost savings being passed on to the consumer. In 1952 the Upjohn Company discovered a much cheaper microbiological process for producing corticosteroid hormones, but Upjohn continued to charge the same prices as those listed by its rivals, some of whom were producing by the more costly process. (5f). When Parke-Davis discovered a cheaper synthetic method for producing chloramphenicol, it failed to reduce its prices below those of its rivals. Other examples could easily be given.

Since prices bear almost no relationship to costs, the argument that high prices are temporarily necessary in order to recoup research costs for new drugs is suspected. The firm will price so as to obtain the highest price consistent with profit maximization for each drug; the fact that some hypothetical method of research cost allocation should indicate that all research costs had been recouped by January 1, 1967, would not under any circumstances in itself lead to a reduction in price. Price declines might result from reductions in demand, but not, apparently, from reductions in actual process outlay costs, and certainly not for expirations of arbitrary cost allocations. In any event, firms do not specifically allocate research overhead to individual drugs, so the entire argument is without any substance. And even if prices were lowered when allocated research costs had been recouped, the reduction--while welcome--would not be very great since the ratio of research costs to the sales price is so low. Research costs are probably recouped in a time period closer to seventeen months than to the seventeen years of patent protection.

CHAPTER III

The Influence of the Legal and Regulatory Framework on Canadian Drug Prices

Why is the level of Canadian drug prices apparently the highest in the world? Since drug pricing is based chiefly on demand, applying the rule of "what the traffic will bear" would to a first approximation suggest that drug prices would be highest in those countries where per capita income is the highest. And this impression is confirmed by the PMAC's otherwise rather pointless demonstration of the ratio between hourly wage rates and drug prices in various countries. The higher the income, the greater is the demand and the higher the price that can be exacted. Wage rates serve to indicate indirectly the level of per capita income. But since per capita income is still somewhat lower in Canada than in the United Stated, this factor alone would not explain higher Canadian prices. While prices are basically related to demand, from one country to another, other factors are also important and will have to be considered.

Let us begin by considering a North American-based company which possesses product patent control on some drug which it wishes to produce and sell internationally. It will attempt to estimate demand in each country and set prices accordingly. High incomes mean high ability to pay, but the presence or absence of rival producers and competitive products will qualify the firm's ability to discriminate in price solely on the basis of relative per capita income. Factors which influence the policy adopted by a single producer with respect to possible rivals (or even price competitors) are as follows: presence or absence of process and product patents in the foreign country; tariffs, quotas, or other impediments to free foreign trade; presence or absence of price controls on drugs; the status of the existing drug industry in a given country, and similar factors. Of these, by far the most important is patent policy, since it will most directly influence the ability of different companies in different countries to compete with a product for which shipping charges, owing to small bulk, are very low, and where manufacturing costs are so low relative to price that customs duties ordinarily would not act as a major deterrent to drug imports.

A company may decide to produce all of its output of a drug domestically and simply sell the finished product in foreign countries, perhaps at price levels much lower than those charged in the very city of manufacture. Or it may pay to establish factories abroad, not necessarily because the wage rate is lower abroad (productivity per hour may also be lower; besides, wages are only a minor part of costs) but because there may be a higher tariff on imported finished drugs than imported raw bulk drugs, and the cost of converting the powder to finished dosage forms may be less than the difference in applicable tariff rates. There is probably little point in the contention that drugs can be sold at lower prices in some foreign countries because production costs are lower abroad. Production may not even be undertaken in the country; if it is, the costs when adjusted for productivity differences may be higher than in the home country. The basic reason for lower prices in such countries is simply lower per capita income; lower wage rates cause low prices by reflecting low incomes, not low production costs.

In Canada there are five major elements in the legal framework which influence the level of drug prices directly and indirectly:

A. the patent and trademark laws

B. tariffs and anti-dumping laws

C. the federal sales tax

D. the Food and Drug laws and

E. legal sanction for the practice of brand-name prescribing.

Each of these elements will be discussed below.

A. The effects on drug prices of the patent and trademark laws.

Drug buyers in Canada are fortunate in that (1) drug product patents may not be obtained independently of process patents, and (2) drug patents are subject to compulsory licensing under normal circumstances. In contrast, patent protection is absolute in the United States. Why, then, have Canadian drug prices remained at higher levels than those charged in the United Stated?

There are four respects in which the present state of Canadian patent law contributes to high drug prices. First, relatively few applications have been made for compulsory licenses, and none of the firms which have been granted licenses have been truly major factors in the international or even domestic drug industry. Second, applications for licenses to import have been refused. Third, since the products of firms selling under compulsory license are usually marketed under generic names, or under little-advertised brand names, the burden of securing a market in competition with the highly promoted brands of major firms, taken in conjunction with the habit of brand-name prescribing, and the disparagement activities of major firms against generic name drugs, puts even the successful applicant for a compulsory license in at best an inferior position in the market. He may undercut his rivals by selling at prices only a tenth as high as theirs, and yet not be able to gain even a tenth of the market. Such an outcome would be unthinkable in any sort of competitive market, and must be attributed to sales promotion and prescribing practices, which are supported by patent exclusivity. Fourth, if a firm produces or imports a drug which is covered by a Canadian process patent, the burden of proof is on the producer or importer to show that the drug was produced by a non-infringing process, and costly and vexatious legal problems abound here.

1. Paucity of Applications for Compulsory Licenses

The first of these reasons is probably the most important. If major firms were awarded compulsory licenses to produce drugs patented by their rivals, the number of major sellers with brand names acceptable to physicians would increase, and the likelihood of price competition would similarly increase. If Parke-Davis were awarded a compulsory license on a Pfizer drug patent, Pfizer, however, would be most likely to retaliate by demanding to be licensed under a Parke-Davis patent for some other drug, and the number of drugs being sold by many major firms would increase rapidly, with price competition becoming increasingly likely. The major firms, however, are well aware of this, and since the Canadian market is only a small part of the total world

market of most of these firms, they hesitate to take actions which might at best increase sales in only perhaps five or ten per cent of their total market, which might eventuate in profit-destroying price competition in Canada, and which would also make for hard feelings among the companies in other markets and disrupt the community of interest in world market stability. It is instructive that compulsory licenses have been obtained chiefly by wholly Canadian firms. If, however, the entire North American market were thrown open to compulsory licensing, the profit prospects of obtaining a license to market a rival's product in a market as large as that of the United States and Canada combined would very likely be too great a temptation for the major international firms to resist. This is particularly true as between the United States and Canada, since journal advertising in the United States would also be read in Canada to a considerable extent. Hence, the adoption of compulsory licensing in the United States would be of very great benefit to Canada.

Unfortunately, this is not likely to happen, The best solution would then seem to lie in the area of enabling those presently price-competitive elements of the Canadian drug market--chiefly the small, Canadian-owned firms--to be able to compete more effectively with the major foreign patent-holding firms. Measures should also be taken to induce new entry by price competitors. If about 90 per cent of the Canadian drug industry is presently controlled by firms which do not choose to take advantage of compulsory licensing, then steps should be taken to increase the viability of the existing competitive segment of the market, and to introduce new competition, if necessary from abroad, in the interest of lowering Canadian drug prices.

2. Failure to Grant Licenses to Import

Second, the failure to grant compulsory licenses to import prevents Canadians from being able to buy foreign drugs at low prices. The reluctance to grant licenses soley for importing is probably due

to the notion that Canada would gain more by having drugs produced domestically than by being able to buy drugs more cheaply. Naturally this is contrary to the principles of international trade and the theory of comparative advantage. But such theories do not impress practical men, who would rather explore the costs and benefits expected from adopting alternative policies. Accordingly, if Canadian drug prices could eventually be cut by 50 per cent, which is by no means impossible, consumers would realize annual savings of about 100 million dollars, even at present rates of consumption. In contrast to this, the industry only employs about 10,000 people in Canada; the industry would by no means be destroyed by a 50 per cent price decline, since costs can be cut by more than 50 per cent; and even if drug industry employment were to decline, it is overly pessimistic to assume that those who become umemployed could not find other, and probably more productive jobs. Above and beyond this, a practical man might have doubts about the extent to which a foreign-owned captial-intensive industry is an unequivocal asset to a country.

As regards employment, wages and salaries paid by drug firms represent only about 30 per cent of the value of output, while in most industries it is closer to 70 per cent. As comparing two domestically owned industries, the ratio of wages to value of product is not too significant, particularly if the industries are competitive, since the addition to total national productivity of a dollar of wages would be about the same as that of a dollar of rent, interest, or profits. But in a monopolistic industry profits (and hence dividends and retained earnings) may be inflated relative to wages. And if the industry is foreign-owned, the dividends will be withdrawn from the direct stream of spending within Canada. To the extent that earnings are retained and reinvested in the industry, the effect is but little different, since foreign claims on Canadian-based facilities are increased, and the basis for the future earning, and possible repatriation, of profits and dividends is increased.

The practical man may argue that the real danger lies in the monopolistic nature of the industry, and not in the fact that it is foreign-owned--after all, dividends received by foreign stockholders may be spent in buying Canadian exported goods. True. However, this is a return to the theory of comparative advantage--scorned by practical men--and it is inconsistent to argue that, on the one hand, Canadians benefit by paying high prices for drugs since this allows some domestic production of drugs, and on the other hand to maintain that the dividends exported by foreign-owned drug plants do not penalize the Canadian economy since they probably lead to increased demand for Canadian exports by stockholders. In one case, only the direct effect of a single aspect of the matter--wages received by Canadians employed in foreign-owned drug plants--is appraised; in the other case there is an appeal to consider both the direct and indirect effects of dividends sent out of the country. Of course it is preferable to analyze both the direct and indirect effects of all aspects of a situation. In general international monopoly, like any monopoly, is a burden on the world economy, although the incidence of this burden may vary from country to country. But there is no general presumption that investment in foreign subsidiaries *per se* is necessarily a net burden or net benefit to the economies of any of the countries concerned.

The point should be stressed, however, that the chief beneficiary of the patent monopoly is the stockholder. The price of anything of value is determined by supply and demand. If supply is short relative to demand, price goes up. When a drug firm gets a patent on a profitable new drug, its expenditures on research, on marketing, and on production will go up. So will its profits. But while the existence of a profitable drug industry provides for the employment of many research scientists, salesmen, production workers, and even management executives, the wages and salaries earned by these men will not be increased by the profitability of the new product. They are members of competing groups, competing against each other for employment in drugs and in other industries. If the drug firm's demand for research workers increases, the increase in their wages will be

limited by the extent to which research workers are willing to leave other industries and work in drugs, and also by the extent to which students are motivated to enter research training in the prospect of good job opportunities. If there were only a dozen or so qualified research workers in the drug industry, they would have a sort of monopoly on research ability and could demand higher salaries as the profits of drug firms went up. But since the number is large relative to the demand, competition among research workers for job opportunities in drugs will keep drug research wages from rising above the level of such wages in similar occupations in industry as a whole. Furthermore, the fact that high earnings today stimulates training and increases supply in the future tends to limit the increase in research salaries, even if total employment opportunities continually expand. The same is true of drug firm executives; if a company president demands a salary increase because of the increased profitability of the firm, he can always be replaced by an executive of comparable ability, recruited from another industry if need be. But the patent creates an artificial scarcity of the capacity to derive benefit from the invention, and this capacity is vested entirely in the ownership of the patent by the stockholders of the firm. The surplus of drug revenues over the corresponding costs of obtaining drug labor, and materials and research, and sales, and management services at competitive market prices and salaries, is reaped entirely by existing stockholders as the return to the truly "scarce" factor in drug production. Hence the most striking thing about the drug industry is the vast increase in the market value of the stocks of the most successful companies, such as Smith Kline and French. There has been no corresponding fantastic increase in production worker wages or management salaries. Hence the country of residence of the stockholders of a drug firm will always be a factor of some importance in estimating the international incidence of drug industry prosperity.

3. Possible Patent Reforms

What, precisely, is the advantage of issuing compulsory licenses to import drugs, in contrast with other ways of weakening the

power of the patent privilege? A range of possible remedies is conceivable:

a. complete abolition of all drug patents, as recommended in the Report of the Restrictive Trade Practices Commission;

b. allowing compulsory licenses for imports;

c. facilitating the process of obtaining compulsory licenses;

d. amending the patent law to put the burden of proof in infringement suits on the plaintiff; and

e. amending section 19 of the Patent Act to allow provincial governments and their agencies to use drug patents upon payment of reasonable compensation, a power presently reserved to the Government of Canada.

The securing of the four latter reforms might make the more radical step of abolition of drug patents unnecessary. Let us consider the implications of these reforms.

a. Abolition of drug patents

The abolition of all drug patents would surely be the most direct single measure to secure new entry and price competition. This would admittedly have the disadvantage of creating international difficulties between Canada and countries committed to drug patents, and the danger of repercussions cannot be discounted. Other costs of patent abolition might also be urged: the possible reduction in research outlays in Canada; the diminution of the stimulus to improve processes which is provided by drug patents; and the possible return to secrecy instead of disclosure on the part of drug inventors. However, since so little research is actually done in Canada, the maximum possible reduction would not be very great. And it is possible that research in Canada might merely be diverted from private to public channels with probable increases in the value of the results. As to the next point, it is likely that the existence of patent protection for drug processes does stimulate development of alternative processes, but it is not certain that this incentive is necessary, nor that the inventions so devised are superior--all that is required to surmount the patent barrier is that the processes be different. As to the return to a policy of secrecy,

it may be observed that almost all Canadian patents are foreign-owned and have already been patented in the country of the inventor, so that the granting of a Canadian patent is not necessary to provide disclosure of the details of the invention to interested Canadians. Furthermore, the "know-how" may remain secret even though the patent discloses the nature of the process. (1g). Genuine secrecy, however, Professor Fritz Machlup of Princeton University has declared, is not really possible in the drug industry, even in the absence of patents, for a variety of reasons including the ability of technicians to analyze and duplicate drug products.

b. Permitting Compulsory Licenses to Import in Conjunction with other Reforms.

If prospective importers were licensed to import drugs produced by Canadian patent holders in return for the payment to the patent holder of reasonable royalties, the potential for competition would be greatly increased. Presumably the international repercussions would be less severe since patents are not abolished, and royalties are paid on quantities imported. This solution has much to recommend it, since it would introduce competition for those drugs which can be produced more cheaply abroad than by domestic compulsory licensees.

Other reforms could be instituted in conjunction with the licensing of imports. The facilitation of the process of obtaining compulsory licenses is a necessary part of any patent reform program which retains compulsory licensing. The time and expense to applicants should be cut to the minimum; if this minimum still proves burdensome, patent licenses should be issued as of right. This is the recommendation of the Ilsley Commission, and it seems highly appropriate. The amending of section 41 (2) of the Patent Act to put the burden of proof on the plaintiff in an infringement suit would probably lead to more competition through the importation of drugs produced abroad by non-infringing processes. Since such imports would be royalty-exempt, they might be sold at even lower prices on the domestic market than the drugs imported by compulsory licensees. But placing the burden of proof on the plaintiff would not completely eliminate the danger of legal harassment

of importers by patent holders. The only way to accomplish this would be to amend the Patent Act.

Section 19 of the Patent Act could be amended to allow provincial governments and their agencies to use any drug patent in return for payment of reasonable compensation, a right which is presently limited to the Government of Canada. This recommendation of the Hall Commission is highly appropriate since it would further safeguard the Canadian drug buyer against restriction of supply and high prices. These four reforms should jointly achieve the same goals as the abolition of patents. If they do not succeed in stimulating price competition and price reductions, then as the Hall Commission indicated in its report, there would be no alternative but to abolish patents.

One final point remains. Applications for compulsory licenses may also be discouraged because of the necessity of a new firm to engage in expensive sales promotion in order to obtain business in competition with sellers of established brand name products. To be forced to engage in such outlays, of course, would reduce or eliminate the ability of the licensee to undersell the patent holder. The solution to this difficulty lies in requiring that brand names for drugs be outlawed and that drugs be advertised and sold only under generic names, coupled with the name of the seller. This aspect of reform will be discussed below under section (5), the effect on drug prices of laws supporting brand-name prescribing.

4. Drug Prices and Trade Mark Reform

Certain provisions in the Trade Mark Act serve to insulate still further the Canadian drug industry from competition in the world market. A foreign parent drug company, in the United States, for example, may be selling a drug at a much lower price in the United States than its Canadian subsidiary is charging in Canada, although both companies are selling the same drug under the same trade mark. Canadian prices could be lowered if it were possible for independent Canadian importers to buy drugs from wholesalers in the United States, pay import duties, and sell the drugs in Canada at a lower price than that

specified by the Canadian subsidiary of the United States manufacturer. This is prevented by the present provision of the Trade Marks Act, which permits the owner of a Canadian trade mark to monopolize the importation and distribution of any product bearing this mark, whether or not any production of the product is carried on in Canada.

This could be corrected by adopting the Hall Commission's recommendation that Section 20 of the Act be amended to specify that no infringement could be claimed where the drugs in question are produced by a related company. (Section 2(r) of the Act defines related companies as "companies that are members of a group of two or more companies, one of which, directly or indirectly, owns or controls a majority of the issued voting stock of the others.") The only retaliation would then be for the Canadian subsidiary to take out a new trade mark for its drug, but it would hesitate to do so to the extent that sales promotion efforts in both the Canadian and United States markets had made the trade-marked name itself a valuable business asset, which would occasion a capital loss upon name change. (see Appendix D for a discussion of the arguments advanced by the Patent and Trade Mark Institute of Canada against patent and trade mark reform.)

B. The Effects upon Drug Prices of the Tariff and Anti-Dumping Laws

Tariffs are intentionally designed to protect domestically situated producers by imposing an import tax burden on foreign goods, thus increasing the cost of imports and raising the prices at which they must be sold in order to justify importation. Except perhaps in the very long run, tariffs tend directly to increase domestic prices by encouraging higher cost domestic producers at the expense of lower cost imports. Hence the complete eradication of drug tariffs would be the most expedient tariff measure for maximizing the potential decrease in Canadian drug prices. But if it is desired to retain protection for domestically situated producers, in the hope of some long-run benefit on the price level, or for the sake of advantages which are considered to outweigh the price-increasing effects of import taxes, the customs laws should then be such as to give protection only to those drugs which are actually being produced at any given time. It would then be

appropriate to revise these laws to accomplish the following goals:

1. the application of tariffs only to those drugs of a class or kind actually produced in Canada;
2. the application of anti-dumping duties only to those drugs of a kind actually produced in Canada;
3. the valuation for customs and anti-dumping duty purposes of imported drugs at levels which are not so high as to motivate foreign parents of domestic subsidiaries to take a disproportionately large share of the total profits of the integrated operation in the foreign country; and
4. the imposing of a schedule of tariff rates no higher than is needed to afford domestic drug plants the minimum necessary protection.

Each of these will be discussed in the following paragraphs.

1. Applying Tariffs only to Drugs of a Class or Kind Actually Produced in Canada

The amending of the tariff laws so as to restrict the application of drug tariffs to drugs of a class or kind actually produced in Canada would aid the cause of price reduction (though in itself it of course would not insure price reductions) by reducing the cost basis of importers, and hence permitting some decrease in price. At the same time, since these drugs would by definition not be of a class or kind made in Canada, the operations of domestic drug makers would not be disrupted. It might be desirable to abolish tariffs on all drugs of a kind not made in Canada, except that since many drugs which are not chemically identical are actually largely substitutable for one another, the exempting from tariffs of individual drugs not made in Canada might be prejudicial to the ability of therapeutically similar but chemically not identical drugs made in Canada to compete in the market with tariff-exempt imports. Nevertheless, "class" should not be defined so broadly that, for example, all antibiotics are considered to belong to a certain class such that tariffs would be imposed on every imported antibiotic if even a single antibiotic were made in Canada. Rather it would be preferable (although admittedly difficult) to define "class" by making an exhaustive enumeration of all drugs which are therapeutic

substitutes for drugs made in Canada, and then exempting from tariffs any drugs not on the list. In addition, the change in the law would not prevent the establishment of new domestic drug plants since tariffs would become applicable to imports of any drugs of a class or kind produced by domestic plants as soon as domestic production were to be established.

2. Applying Anti-Dumping Duties only to Drugs of a Kind Actually Produced in Canada

The existence of the anti-dumping duty tends to motivate foreign parents of Canadian subsidiaries to impute a larger share of total profits to the parent by setting prices to the subsidiary at levels high enough to avoid all possibility of being subject to the anti-dumping duty. Clearly, the determination of the price below which the duty will be imposed is a matter of great importance. To set too high a price would be to penalize the Canadian subsidiary and add to the total costs which it must recoup in prices, thus adding yet another factor which conduces to higher prices. But setting too low a price will result in lower tariff revenues and less protection to domestic Canadian producers, although at the same time this may reduce costs and thus permit (but not insure) some price reductions. Complete abolition of the anti-dumping duty would eliminate this particular parent-subsidiary complication from arising, but of course would leave domestic producers open to the threat of dumping. It would seem desirable to limit the application of the anti-dumping duties to drugs of a kind made in Canada. At present, while most of the pharmaceutical drugs used in the preparation of dosage forms in Canada are not themselves made in Canada, most pharmaceutical preparations containing these pharmaceutical drugs are considered to be of a class or kind made in Canada for dumping duty purposes. Hence although the active ingredients in a drug are not made in Canada, dosage forms containing these drugs may be subjected to anti-dumping duty in order to protect sellers of dosage forms rather than the non-existent manufacturers of the basic drugs from which the dosage forms are prepared. Drug prices are therefore increased by the amounts of anti-dumping duty paid, or by

the increase in invoice prices necessary to eliminate the danger of anti-dumping duties, not only for drugs made in Canada, but for all other drugs of a general class which are made in Canada. It would seem desirable to limit the application of anti-dumping duties to drugs of a kind made in Canada, in order to eliminate the possible price-increasing effects of the possibility of imposition of anti-dumping duties on all drugs of the same class sold in Canada. This would maintain the protection afforded the actual manufacturer of the basic drug, but not the protection now enjoyed by the seller who, rather than making the basic drug, merely imports it or its ingredients. This difference in treatment can be defended on grounds that it is the manufacturing of the basic drug which is primarily to be protected because of the greater investment of the manufacturer in more specialized facilities, and the greater flexibility of operation of the importer of finished dosage forms or ingredients thereof.

3. Valuation of Imported Drugs for Tariff Purposes

The reduction in the scope of anti-dumping duties would eliminate many of the instances in which valuation problems for imported drugs arise. The goal of valuation for customs purposes of those imported drugs which are still subject to dumping duties, at levels which are not so high as to motivate foreign parents of Canadian subsidiaries to take too large a portion of the combined profits of parent and subsidiary in the foreign country, would be most expeditiously arrived at by setting this value equal to production cost plus an allowance for gross profit. Gross profit would include allowances for general and administrative overhead, selling costs, and net profits. To simplify the administration of this rule, some maximum allowance for gross profit should be stipulated. This is now done for some items of import. For example, the maximum gross profit allowance for imported car parts of a class or kind not made in Canada

is five per cent. If after appropriate study a maximum rate of perhaps ten per cent were to be adopted for drugs, the motivation for foreign parents to charge high prices to Canadian subsidiaries to avoid anti-dumping duty would be removed. If, for example, a drug cost $1.00 to produce, invoice costs to Canadian importers of less than $1.10 would not be subject to dumping duty. If invoice costs were over $1.10, then the actual invoice cost would naturally be the basis for the regular tariff duty. But by setting only a reasonable maximum allowance for gross profit, foreign parent companies would not be inclined to set high invoice prices to subsidiaries to avoid anti-dumping duty.

4. Reduction of Tariff Rates to Minimum Levels Consistent with Protection of Domestic Producers

Finally, the tariff rates imposed on drugs should be no higher than is necessary to afford domestic producers the minimum protection considered necessary. A careful evaluation of the entire schedule of tariffs on drugs is needed, such as was proposed by the Hall Commission. The Tariff Board has recently finished a study of the chemicals items tariffs, which however specifically excluded pharmaceuticals. Still, many fine chemicals used by the drug industry were evaluated, and the Tariff Board should be directed to make a similar study for drugs.

There are two respects in which one might be skeptical about the value of customs reform in achieving reductions in the price of drugs. First, it may be asked whether or not a reduction in tariffs would be passed on to the consumer in the form of lower prices, or whether the net effect would be to reduce tariff revenues and leave prices unchanged. The answer would appear to be that tariff reduction, by itself, would not necessarily lead to price cuts because of the presently non-competitive nature of the industry. If, however, tariff reductions are only one part of a concerted program to make the industry more competitive, then the nature of the resulting competition will force drug firms to reduce prices as their total cost levels are reduced.

A second objection is that even if price reductions did follow as

a result of tariff reductions, the resulting price declines would be very small. Minister of National Revenue Benson has made a statement to this effect to the Committee:

> "Not only are customs markups low as compared with industry profits, but also the factory costs to which they apply are low in relation to the total costs incurred in marketing pharmaceuticals. Thus the values for duty now prescribed under section 38 of the Customs Act are low in terms of normal selling prices in the industry, and for this reason there is some doubt that any lower valuation would greatly reduce the price of drugs in Canada." (7n).

Again, it must be admitted that if tariff reductions alone were relied upon, the effect would very likely be negligible. But if other measures are also employed to create price competition, prices would decline and the size of the tariff relative to consumer prices would become greater. Industry profits and the total cost of marketing drugs would be forced to decline, so that values for duty purposes would become a larger part of the lower price levels prevailing under competition.

C. The Effect on Drug Prices of the Federal Sales Tax.

Because of the nature of demand for prescription drugs, a tax at the manufacturer's level can be pyramided through the various stages of distribution and passed on to the consumer in magnified form. An eleven per cent manufacturer's sales tax would thus increase the price to the wholesaler by eleven per cent; and the wholesaler, who can be depended upon to impose his traditional markup, will raise his price to the retailer by the same eleven per cent. The relationship between the retailer's cost and his price has been disputed. If the druggist simply marked up his cost for the drug by the traditional 66 2/3 per cent markup, the impact of the tax would then be to increase the final consumer price by eleven per cent. If, on the other hand, he superimposes some fixed charge to the marked-up cost, the net effect on the price to the buyer would be an increase of less than eleven per cent; to the extent that the ratio of the fixed charge to the cost-plus-markup was relatively large, the price increase to the buyer might be appreciably less than eleven per cent. If, however, the average prescription were priced in such a way as to make the price to the buyer exactly twice as high as the cost of the "ingredients" to the druggist (this is the relationship

shown in the Canadian Pharmaceutical Association's annual surveys) then the eleven per cent sales tax on the manufacturer would on the average be passed on to the consumer as an eleven per cent price increase. (See Appendix A for a detailed discussion of the impact of the sales tax on the consumer price under different assumptions regarding the method of pricing prescriptions.)

The presentations submitted to this Committee have been practically unanimous in recommending the abolition of the sales tax as a way of reducing the price of drugs. But it must be stressed that the act of tax abolition, taken by itself, would not necessarily have the slightest effect on prices. Prices are determined by demand, and if drug sellers are able to exact $11.00 from the drug buyer for a particular item, why should they reduce the price to $10.00 just because the manufacturer now pays 55 cents less in taxes on a price to the distributor of $5.55? He could quite readily just pocket the extra 55 cents and not change the price to the distributor. And even if he reduced the price to $5.00, the wholesaler and/or the retailer might simply widen their margins correspondingly and the net price to the consumer would be unchanged. To be sure, the present publicity being given to the high price of Canadian drugs, and the suggested remedy of sales tax removal, has no doubt focussed so much attention on this issue that it would be difficult for sellers not to pass on at least a good part of the tax savings to buyers. But arguments against the immediate reduction of prices because of higher-priced existing inventories, although valid in themselves, may be used as a delaying tactic, and price cuts may be postponed until public awareness of their possibility has abated. By the time that the higher-cost inventories have been sold, smaller price reductions than are justified may be made because of this abatement of interest. And even if full price reductions are made, the knowledge on the part of sellers that extensive sales can be made at prices eleven per cent higher may act as an incentive to subsequent price increases to restore prices to former levels. All of this is speculation, but the uncompetitive nature of the drug industry suggests that such speculation is not entirely idle. Drug industry spokesmen have

clearly been stressing the price-increasing effect of the sales tax in order to distract attention from drug firm marketing costs and profits. Sales tax abolition is certainly justified on many grounds, but must be only one part of a comprehensive reform program to introduce genuine price competition into the Canadian drug industry.

D. Effects on Drug prices of Food and Drug Laws and their Administration

The Canadian food and drug laws appear to provide adequate authority for public inspections of the facilities and products of drug sellers. But it has been argued that sufficient funds and staff to guarantee adequate inspection have not been appropriated. The necessary funds should by all means be supplied. One of the greatest advantages of the major firm is its ability to disparage the quality of the products of lower-priced generic sellers. That it can successfully do so despite the fact of federal inspection is proof of its ability to disparage the possible scope of the efforts of inspections as well. If sufficient funds are appropriated to make the adequacy of the inspection program obvious to all, these disparagement efforts will become manifestly specious. Such an expanded inspection budget is an essential part of a drug industry reform program, since the awarding of licenses to import will increase imports of low cost drugs, and the drug industry can be expected to mount a titanic effort to disparage the quality of imported drugs and hopefully prevent their prescription. It is my understanding that the present level of drug imports has already prompted the assignment of drug inspectors to some Canadian embassies in drug exporting countries, so that foreign factories can be inspected as well as their products.

Steps should also be taken to eliminate any unnecessary barriers to the marketing of "new drugs" by a large number of firms. Where a new drug has been cleared for marketing on the basis of experimental and clinical information compiled by an original applicant, the identical drug should automatically be cleared for marketing by any firm demonstrating the ability to produce an identical drug, regardless of possible differences in the processes of manufacture. To act otherwise is to prolong the monopoly power period of the original applicant, and to impose unnecessary

burdens on later applicants.

E. The Effect on Drug Prices of the Laws Supporting Brand Name Prescribing

Brand name prescribing adds very greatly to the cost of many drugs, and is engaged in not because medical schools teach brand name prescribing (this is not their practice) but because of the great volume of brand name sales promotion to which they are exposed. One way of reducing drug costs by making it possible for the druggist to dispense the generic equivalent of the brand-name drug being prescribed is to amend provincial pharmacy acts to permit such so-called "substitutions."[1] This was of course done in Alberta in 1962. See Appendix E where the statute is reproduced. The Alberta law authorized "substitution" provided that the physician did not specify that no substitutions were to be made. But even with this law in force, it is by no means certain that the average pharmacist would have substituted lower-priced drugs for brand-name drugs since his profit margin on the former is likely to be much lower than on the latter. Indeed, even if a prescription is written generically, it will usually pay to fill it by substitution of a brand name drug at higher prices. According to a survey conducted some years back by Drug Merchandising 62 per cent of generically written prescriptions are filled with a brand name product, and only 30 per cent are filled with a generic product. (1h). Very many drugs are subject to patent monopoly so that generically written prescriptions must necessarily be filled with a brand name product. For other drugs which are sold under both generic and brand names, the demand for the unadvertised generic name product may be so small that its distribution

---

1 To an economist, the notion that any meaningful "substitution" has taken place when one company's embodiment of a particular chemical is selected rather than that of another, is a curious one. And indeed, in the United States the economist's view coincided with that of state pharmacy boards until relatively recently. One of the most fascinating developments unearthed by the Kefauver hearings, and one of the least publicized, was the success of the National Pharmaceutical Council's crusade to change the meaning of substitution. Substitution used to mean dispensing the wrong drug, not a different brand name. In 1953, when the crusade began, only four states in the United States had any kind of anti-substitution laws. By 1959, 44 states had written into their law books the new approach to substitution. Fortunately, a similar attack on hospital formularies proved much less successful. (5g).

is limited largely to hospitals or major cities. Hence, for many reasons, even the mandatory requirement that all prescriptions be written generically would not necessarily result in cost savings for any very large fraction of prescriptions.

A genuine solution of this problem must await the outlawing of brand names for drugs. If drugs had to be marketed under the generic name, coupled with the name of the manufacturer, the power of massive sales promotion to "educate" the physician to prescribe only a certain brand name would be eliminated, and the ability of identical substances to masquerade behind different brand-name disguises would be at an end. Furthermore, generic names would soon be disciplined. If Lederle had to sell "Declomycin" under the name "Demethylchlortetracycline-Lederle" and Sandoz had to sell its euphonious "Mellaril" as "Thioridazine hydrochloride-Sandoz," drug firm spokesmen would soon drop arguments that generic names cannot be simple, and begin to make every effort to simplify them. A further advantage would be that Canadian physicians who read medical journals published in the United States would not be subjected to advertising appeals which could be translated directly into prescribing in Canada the brand names advertised.

It would be far more rational to advertise by firm name than by brand name. The alleged virtue of prescribing by brand name is to secure the high quality products made by the reputable firm. But the brand name does not identify the firm; instead, it refers to absolutely nothing but itself, stressing uniqueness and abstraction. It is probable that many physicians do not know which firm produces many of the brand names which they prescribe; indeed, with the striking proliferation of brand names, it could hardly be otherwise.

It should be kept in mind that the physician's hesitance to prescribe generically is relative, not absolute. They readily abide by hospital formulary agreements. Presumably this reflects greater confidence in the hospital pharmacist and the facilities at his disposal than they have in the retail druggist. Adequate public inspection of drug products should result in all pharmacists being equally worthy of confidence.

The outlawing of brand names is probably essential to any rapid reduction in Canadian drug prices. When reasonably priced generic drugs begin to be imported, their impact on the market will be determined by the willingness of physicians to prescribe them, as well as by their probable success in obtaining sales on tender from hospitals and public agencies. If the doctor is not aware of the generic name of a particular brand name drug, it will not be convenient to prescribe it generically. And advertising certainly minimizes the attention devoted to generic names relative to brand names. Beyond this, the practice of brand name sales promotion creates a presumption in favor of brand names and against generic names, which is miseducational in the sense that it conflicts with what medical students are almost universally informed in medical schools is rational prescribing practice. Newly graduated physicians will not be subject to efforts to make them forget generic names. For older physicians, it is likely that the "magic" of brand names will not long survive the passing of such names. Depending upon the intensity of price competition, and the rapidity with which it develops, the ability of major firms to finance extensive sales promotion will sharply decline as prices and cash flows fall, and the present advertising-induced disadvantage under which the generic name seller labors will be greatly reduced. As the ability of public inspection to keep all low-quality drugs off the market is established, there will be less fear of prescribing generically.[1]

Other laws conducive to promoting an environment supporting brand name prescribing and the suppression of price competition would include provincial legislation limiting operation of drug stores to registered pharmacists, and limiting the dispensing of prescriptions to

---

1 This carefully cultivated suspicion of the quality of generic name drugs is largely unjustified; many generic name drugs are no doubt superior to brand name drugs. In the United States, FDA records show that irregularities have repeatedly arisen in connection with the drugs produced by brand name firms. A generic name is no indication of low quality. It is equally true that a brand name in itself is no guarantee of acceptable quality.

licensed pharmacists, physicians, dentists, and veterinary surgeons. obviously it is possible for entry to pharmacy to be limited by requiring unnecessarily lengthy academic preparation, the passing of examinations of arbitrary difficulty, and the imposition of apprenticeship requirements. While no one wants incompetent personnel to dispense prescriptions, the requirements for success in pharmacy today probably put a higher premium on merchandising skills than on compounding and other technical skills. Requirements could be correspondingly altered. To stimulate price competition at the retail drugstore level, it is absolutely essential that it be made possible for persons and firms not subject to possibly arbitrary pressures or penalties imposed by pharmacy control boards to enter the field. The competition provided by discount pharmacies, drug chains, and the equivalents of drug supermarkets and mail order houses should do a great deal to lower drug prices and force the conventional type of pharmacy to become more efficient.[1]

---

1 The statements made to this Committee by Mr. S. S. Bass of London Drugs, Limited, Vancouver, at least suggest that improper pressures may be brought to bear on pharmacy owners who engage actively in price competition. (7mm).

CHAPTER IV

The Effect of Drug Law Reform on Existing Canadian Drug Firms

The existing Canadian drug industry is more than capable of dealing successfully with the drug reforms proposed in this submission. The major firms have a tremendous initial advantage over new entrants selling under generic names or unknown brand names in that their intensive sales promotion campaigns have secured for their brand name drugs the good opinion of the medical profession, and the custom of disparagement has placed generic name sellers at a great disadvantage. If brand names are outlawed, the name of the seller will still stand established firms in good stead. But it is to be expected that the availability of compulsory licenses to import, in conjunction with the other proposed reforms in drug laws and in the distribution system, will force existing large firms to respond to the challenge of price competition. It is a challenge which they are well able to meet, since their production costs are very low, and probably lower than those of most of the importers because of their larger volumes of output. To meet the low prices of imported drugs, it will be necessary to reduce marketing costs greatly, and to settle for the lower rates of return on investment which are everywhere imposed by competition. It will, in a salutary sense, force the firms to become much more efficient in their overall Canadian operations.

The total sales volume of the major firms will be maintained to the extent that they reduce their prices to meet the competition of imported drugs. It is to be expected that the chief impact of these imports will be to drive the prices of the major firms down a little closer to their costs, which are no doubt low enough to allow a great deal of price reduction. The impact on employment and investment in Canada will probably not be severe since the principle of tariff protection for the domestic industry is not being abandoned. Furthermore, since much of the industry's employment is concentrated in the Montreal and Toronto areas, the chances that any displaced workers will find employment elsewhere is correspondingly great.

In summary, it is to be expected that the major effects of drug reform will be to reduce the prices, selling outlays, and profits of existing large drug firms, rather than to decrease greatly their share of the market. Output can be maintained to the extent that they are willing to cut prices to meet the challenge of imports, and this will maintain output and employment for Canadian-based plants. Even research may not suffer much if fiscal incentives and subsidies to research continue to expand.

CHAPTER V

Summary of Recommendations

1. Compulsory licenses to import should be granted, subject to the payment of reasonable royalties. These licenses should provide for the importation of semi-finished and finished dosage forms as well as bulk drugs.
2. Section 41(2) of the Patent Act should be amended to put the burden of proof of infringement of drug process patents on the plaintiff.
3. Every effort should be made to further expedite the process of acting on compulsory license applications. If reasonable expedition cannot be achieved, such licenses should be issued as of right.
4. Section 19 of the Patent Act should be amended to allow provincial governments and their agencies as well as the Government of Canada to use any patented drug, subject to the payment of reasonable compensation.
5. The Trade Marks Act should be amended to allow the importing of trade-marked drugs which have been produced by a company related to the company possessing the Canadian trade mark.
6. The schedule of tariffs on drugs should be reviewed by the Tariff Board, with a view toward:
   (a) Limiting the liability of drugs to tariff duties to those drugs of a class or kind actually made in Canada, and
   (b) reducing applicable rates to the minimum level consistent with the provision of the desired level of protection for domestic producers.
7. Liability for anti-dumping duty should be limited to drugs of a kind actually made in Canada, where "kind" is defined in terms of the active ingredient.
8. The valuation for customs purposes of imported drugs should be based on production cost plus a maximum allowance for gross profit (or invoice cost, if higher) in situations where it is not possible independently to ascertain fair market value.
9. The federal sales tax on drugs should be removed.

10. The Food and Drug Directorate should be provided with sufficient authority, funds, and staff to enable it to carry out an inspection program adequate to prevent the marketing of substandard drugs and establish confidence in all drugs sold in Canada.

11. Unnecessary barriers to the marketing of new drugs by additional firms should be eliminated. Where a new drug has been cleared for marketing on the basis of adequate data compiled by an original applicant, the same drug should be approved for marketing by any firm capable of producing the identical drug. Similarly, unnecessarily onerous burdens in the way of supplying drug information which merely duplicates existing known information should not be imposed.

12. The publication of a governmentally sponsored newsletter evaluating drugs, similar to the Prescriber's Journal in Great Britain should be considered, particularly if widespread subscription by Canadian physicians to presently or prospectively published independent newsletters of this type fails to develop.

13. Every reasonable effort should be made to inject more price competition into drug retailing. Serious consideration should be given to the liberalizing of the requirements for operating drugstores and dispensing prescriptions, so that the development of lower priced outlets for drugs such as discount pharmacies and mail order houses can be encouraged.

14. If the above reforms do not succeed in reducing drug prices to competitive levels in a reasonable period of time, drug patents in Canada should be completely abolished.

All of which is respectfully submitted

Henry B. Steele

on behalf of the Government of Alberta

February, 1967

APPENDIX A

An Analysis of the Effects of the Eleven Per Cent Federal Sales Tax on the Price to the Patient for Prescriptions priced by Different Methods.

I. General Analytical Framework.

Let the manufacturer's sales price to the wholesaler, prior to the imposition of the tax, be an amount designated by the letter C. (This is the price per unit.)

Let the wholesaler's markup be the conventional 20% above his cost of C per unit. Hence the wholesaler's price to the retailer, per unit, is C(1.20).

Let the retailer's markup be assumed initially to be simply 66 2/3 per cent above the price which he pays the wholesaler. Hence the price to the patient would be C(1.20)(1.667). If we let this price be represented by the letter P, it is obvious that P-2C. Hence the markups of wholesaler and retailer have doubled the manufacturer's pre-tax price.

If a sales tax of eleven per cent be imposed on the manufacturer's sales price to the wholesaler, the manufacturer can pass the entirety of the tax forward to the wholesaler by raising his price by eleven per cent. The wholesaler's price then becomes C(1.11).

The wholesaler can then realize an increased absolute gross profit margin per unit by maintaining his usual markup of 20 per cent on his increased price from the manufacturer. The price to the retailer will then be: C(1.11)(1.20).

The retailer can similarly realize an increased absolute gross profit margin per unit be persisting in the imposition of his customary markup of 66 2/3 per cent on the increased price from the wholesaler. The price to the patient would then be C(1.11)(1.20)(1.667). Let us refer to this post-tax price as P*.

We now have to answer two very important questions: (1) What per cent increase in the price to the patient was brought about by the imposition of the 11 per cent sales tax at the manufacturer's level? (2) How is this increase in price accounted for by (a) actual tax revenues; (b) the increase in the wholesaler's gross profit margin; and (c) the increase in the retailer's gross profit margin? The answers to these questions can be supplied by a very straightforward analysis.

The first question can be answered by computing the increase in the price to the patient. The ratio of P to P* gives us the percentage change in the patient's price as a result of the tax. This ratio is as follows:

$$(1) \quad \frac{P^*}{P} = \frac{C(1.11)(1.20)(1.667)}{C(1.20)(1.667)} = 1.11$$

Hence the eleven per cent sales tax, shifted forward in full by the manufacturer, and pyramided by the wholesaler and retailer, results in an eleven per cent increase in the price paid by the patient.

To answer the second question, let us assume that the value of P is $1.00 and hence P* is $1.11. This would mean a pre-tax manufacturer's price of $ .50, and a price of $ .60 to the retailer. The patient's dollar would be divided as follows: 50 cents to the manufacturer, 40 cents to the retailer, and 10 cents to the wholesaler. But after the tax is imposed, the manufacturer increases his price of $ .50 by 11 per cent, of 5.5 cents, so the wholesaler pays $.555. If the wholesaler adds his customary 20 per cent margin, the price to the retailer increases by 11.1 cents, to $.666. When the retailer imposes his 66 2/3 per cent markup, the consumer price increases by 11 cents to $1.11. The consumer now pays 50 cents to the manufacturer, 44.4 cents to the retailer, 11.1 cents to the wholesaler, and 5.5 cents to the government in taxes. Although the manufacturer's receipts have not increased, the retailer's gross profit margin has gone up by 4.4 cents, and the wholesaler's gross profit margin has increased by 1.1 cents. Only 50 per cent of the increase in the price to the patient has been captured by the taxing authority; the other 50 per cent has

been allocated to increasing the gross profit margins of distributors. Sales tax receipts are only 4.9% of the post-tax price. ($.055/$1.11).

II. Effect of different prescription pricing methods on the relative price increase caused by the sales tax.

A. Different Pricing Methods employed by pharmacists in Canada:

1. Retailer's cost plus 66 2/3 per cent markup.
2. Retailer's cost plus 66 2/3 per cent markup plus dispensing fee.
3. Retailer's cost plus "professional fee."

It has been reported that some pharmacists do not charge professional or dispensing fees in cases where the retailer's cost plus the 66 2/3% markup would yield an absolutely high markup. (Testimony of Mr. W. Isaacson of the Council of the Ontario College of Pharmacy and proprietor of retail pharmacies in Toronto, as reported in the 1961 Restrictive Trade Practices Commission Hearings, p. 2967.) If the drug were not so highly priced, a dispensing fee of perhaps 50 to 75 cents might be added to the cost plus markup. Alternatively, a "professional fee" of perhaps $2.00 to $2.25 or more might be added to the retailer's cost. It is obvious that the role of the sales tax in increasing the price to the patient may vary as between different methods.

Let us apply each method to the "average" prescription in Canada during 1965, which according to testimony presented before this Committee on June 14, 1966, by Mr. J. C. Turnbull, Executive Director of the Canadian Pharmaceutical Association (page 57 of the Hearings) was priced at $3.32 on the basis of preliminary figures for the 24th Annual C.Ph.A Pharmacy Survey for 1965.

1. Retailer's cost plus 66 2/3 per cent markup. If the price to the patient of $3.32 represents a 2/3 markup over retailer's cost, the retailer must have paid $1.992, and the wholesaler's cost must have been $1.66, or 50 per cent of the price to the patient. The tax paid by the manufacturer must have been 11/111 of $1.66, or 16.4 cents,

so that the net receipts by the manufacturer would have been $1.496. In this case, the price in the absence of the sales tax would have been twice $1.496, or $2.992. The price increase occasioned by the tax is of course 11.0 per cent, as before ($3.32/$2.992), and the ratio of taxes collected to the price paid by the patient is $ .164/$3.32, or only 4.94 per cent. (It is doubtful, however, if a price of only $3.32 would be regarded as sufficiently high to justify omitting a dispensing fee.)

2. Retailer's cost plus 66 2/3 per cent markup plus dispensing fee. If a dispensing fee is charged, one must know the average retailer's cost for the typical prescription in order to compute both the markup and the average dispensing fee. According to Mr. Turnbull's statement, cited above, the average ratio of retailer's cost to prescription price in 1964 was 50 per cent. (Hearings, p. 58). Hence a prescription priced at $3.32 would involve a cost of $1.66 for materials. Adding the 2/3 markup to $1.66 brings the price up to $2.77, and the difference between $2.77 and $3.32 could be interpreted as an average dispensing fee of $ .55.

If this be assumed the case, the price in the absence of the tax can readily be computed. If the retailer's cost was $1.66, the wholesaler's cost was $1.38 (5/6 of $1.66) and the sales tax paid by the manufacturer was 13.7 cents (11/111 of $1.38). The manufacturer's net after taxes was therefore $1.243. In the absence of the tax, the retailer's cost plus 2/3 markup would be twice this sum, or $2.486. Adding 55 cents to this sum, we arrive at the price of $3.036 for the average prescription of 1965 if there had been no sales tax. Hence the increase in price occasioned by the sales tax, under this particular method of pricing, is 28.4 cents, and the relative price increase is $3.32/$3.036, or 9.6 per cent. The ratio of taxes collected to the price paid by the patient is $ .137/$3.32, or only 4.13 per cent.

3. <u>Retailer's cost plus "professional fee."</u> If we a assume, rather conservatively, that the typical "professional fee" charged by Canadian pharmacists during 1965 was $2.00, then for the average prescription of $3.32, this would represent a retailer's cost of only $1.32 for purchases from wholesalers. The wholesaler's cost for this amount would be 5/6 of $1.32, or $.933. The tax paid by manufacturers on this sum would be 9.25 cents (11/111 or $.933). The net to the manufacturers would therefore be $ .841. In the absence of taxes, the retailer's cost for this amount, as purchased from wholesalers, would be $1.009. Adding the $2.00 "professional fee" to this sum, the prescription price would be $3.009. Hence, the increase in price brought about by sales tax, under the "professional fee" system, would be 31.1 cents. The relative price increase is $3.32/$3.009, or 10.0 per cent. The ratio of taxes collected to the price paid by the patient is $ .0925/$3.32, or only 2.8 per cent.

B. Relative effects of sales tax on prices of more expensive and less expensive prescriptions according to method of pricing.

An eleven per cent sales tax will always increase retail prices by eleven per cent if the retailer uses the conventional 2/3 markup alone. Similarly, the sales tax receipts will always be only 4.96 per cent of the post-tax price.

If pharmacists always add a dispensing fee of a given amount to the 2/3 markup over retailer's costs, the effects on prices will vary according to the magnitude of the retailer's cost for a particular prescription. Assuming a conservative dispensing fee of 50 cents, the ratio between P* and P will be given by the following expression:

$$(2) \qquad \frac{P^*}{P} = \frac{C(1.11)(1.20)(1.667) + .50}{C(1.20)(1.667) + .50}$$

If the cost of ingredients C is zero, obviously there is no price increase. But for every one-cent increase in C, the numerator of expression (2) will increase by 2.22 cents while the denominator will increase only by 2.0 cents. Hence for every one-cent increase in C,

the incremental price increase is eleven per cent, but the average price increase will be a great deal lower than this at very low levels of C. Only as C becomes increasingly large will the average price increase approach the ultimate level of eleven per cent. Similarly, if C is zero, taxes collected are zero, and the ratio of taxes collected to retail price is zero. But as C becomes larger and larger, the amount of taxes similarly increases, and ultimately for extremely high values of C, the ratio will be the same 4.96 per cent mentioned in connection with equation (1) above.[1] The table below gives some sample values for prescriptions with various levels of ingredient costs at the manufacturer's level:

Ingredient costs at manufacturer's net after-taxes price levels:	Percentage increase in Prescription Price Caused by sales tax	Ratio of tax receipts to Prescription Prices after taxes
$ .10	3.1 %	1.5 %
.50	7.3	3.4
1.00	8.8	4.0
1.50	9.4	4.3
2.00	9.8	4.5
2.50	10.0	4.6
3.00	10.1	4.7
5.00	10.6	4.8
10.00	10.7	4.8

If pharmacists add a $2.00 "professional fee" to their invoice cost, the effects on prices of the sales tax will still vary directly with the level of cost to the pharmacist, but not as markedly as in the case of the 50 cent dispensing fee. The ratio between P* and P is now given by expression (3):

$$(3) \qquad \frac{P^*}{P} = \frac{C(1.11)(1.20) + 2.00}{C(1.20) + 2.00}$$

---

1 As the value of C becomes infinitely large, the effect of the $ .50 dispensing fee becomes completely negligible. Hence, neglecting the $ .50 in both numerator and denominator, expression (2) becomes equivalent to expression (1).

Again, if the cost of the ingredients is zero, there is certainly no price increase. But for every one-cent increase in C, the numerator of expression (3) will increase by 1.332 cents, while the denominator will increase by 1.2 cents. As in the case of expression (2), for every one cent increase in C, the incremental price increase is eleven per cent, but the average price increase will be a great deal lower than eleven per cent at low values for C. But as C becomes increasingly large, the increase in the total price will approach its ultimate level of eleven per cent. The effect is retarded, however, in expression (3) relative to expression (2) in that the total price includes a component which does not vary with the value of C of $2.00 in the former instance and only $ .50 in the latter instance.

The same comparison between expressions (2) and (3) also holds with regard to the ratio of taxes collected to the after-tax price. This ratio will approach 8.26 per cent as the value of C becomes extremely large, but it will approach this level more slowly than if the fixed fee component were only 50 cents instead of $2.00. The table below gives some sample values for prescriptions with various levels of ingredient costs to the retailer:

Ingredient costs at manufacturer's net after-tax price levels:	Percentage Increase in Prescription Price Caused by Sales Tax	Ratio of Tax Receipts to Prescription Prices after taxes
$ .10	0.6 %	0.5 %
.50	2.5	2.1
1.00	4.1	3.3
1.50	5.3	4.1
2.00	6.0	4.8
3.00	7.1	5.5
5.00	8.3	6.4
10.00	9.4	7.2

III. Evaluation of the Effects of the Sales Tax as applied to Prescription Drugs.

Basic to the analysis of any sales tax is the extent to which it is pyramided. In industries where price competition is largely inactive, and distributors' markups chiefly a matter of tradition or convention, the tax will be dependably and automatically pyramided as

the sellers attempt to shift the tax forward to the final consumer by adding their traditional markups to the tax-included prices which they pay. Where one method of distribution is universally followed, the pyramiding process will occur most smoothly. If some sellers deal with fewer intermediate distributors, other things being equal, they will be able to sell at lower prices than sellers who deal with more middlemen. The present application of the sales tax to prescription drugs makes a substantial, although in all probability not perfect, allowance for this situation by computing the tax on the basis of a 49.3 per cent discount below retail price for transactions between manufacturers not selling in wholesale quantities to independent wholesalers, and such non-wholesale dealers.

Beyond this, the exemptions given to such dispensers as public hospitals and charitable institutions, and to certain particular drugs, introduces a discriminatory factor between different types of dispensing outlets, and/or different drugs. Whether or not such discrimination is socially desirable is a question of equity rather than of economic efficiency. To the extent that tax pyramiding is substantial (and from all indications this is the case for prescription drugs), the sales tax is inefficient in that it induces distortions in relative prices charged (or relative profit margins received) between sellers utilizing different distribution channels, and between exempt drugs as compared with non-exempt drugs. The first sort of distortion should be substantially, although probably not completely, offset by the tax treatment accorded to certain non-wholesaler transactions, but this treatment does not affect the price advantage of hospitals over retail pharmacies. The second sort of distortion, that between exempt and non-exempt drugs, is similarly not affected by any mitigating provisions in the tax laws.

A second question relating to efficiency of any sales tax is this: since the object of revenue taxation is to raise funds for public use, and the price-increasing effect is an undesired by-product,

it would be desirable to minimize the ratio of the price increase to the tax revenues received per unit. To do this, it is expedient to tax at the retail level only, in order to minimize pyramiding, and to tax goods the demands for which are very sensitive to price such that sellers cannot raise prices much without pricing the good entirely out of the market. (Such goods are said to display a high degree of price elasticity of demand.) The prescription drugs sales tax meets neither requirement. Since it is applied at the manufacturers' level, it is pyramided upward at the distributor's level or levels. And since the price sensitivity of demand for prescription drugs is notoriously low, the price-raising effect of imposing a tax will be proportionately very great. For many types of drugs, the price inelasticity of demand is probably nearly perfect, such that the entirety of the pyramided price increase can be passed forward to the consumer without reducing the quantity sold in the market. Indeed, it is for this reason that computations of the price-increasing effects of the sales tax on drugs can be made with considerable confidence.

Under these circumstances, a sales tax applied at the retail level would raise more tax revenues and increase prices by no more than the same tax applied at the manufacturer's level. If the manufacturer's price to the wholesaler were $1.00, the wholesaler's markup would increase the retailer's cost to $1.20, and the 2/3 retail markup would raise the price to $2.00. An eleven per cent sales tax at retail would yield 22 cents in tax revenue and increase the price by the same 22 cents, to $2.22. An eleven per cent tax on the manufacturer's price of $1.00 would raise only 11 cents in tax revenue, but the pyramided price increase would produce the same $2.22 price to the patient. (This example is purely illustrative and should not be taken as a recommendation for Federal retail sales taxation.)

In conclusion, it would seem that the sales tax on prescription drugs has nothing to recommend it. This is hardly surprising since it is difficult to conceive of defending a tax on illness. <u>However, elimination of the tax by itself will not insure any reduction in drug prices</u>; unless active competition is introduced into the market, prices may remain at the levels produced by the tax. While the tax is shifted forward by sellers, the elimination of the tax may not give rise to any "de-shifting", but simply increase drug manufacturers' net receipts by eleven per cent. Thus it is imperative that the elimination of the sales tax be seen as part of a more general program to reduce drug prices by increasing competitive forces in the market, rather than as a reform capable of being introduced in isolation from other reforms.

APPENDIX B

Comments on the Submission of the Pharmaceutical Manufacturers Association of Canada

The Submission to this Committee of the PMAC deserves careful reading since it has been very carefully prepared. Adequate comment would require a document several times as lengthy as the original submission. Hence only a few of the most important areas can be analyzed.

I. The Significance of International Comparison of Drug Prices in Terms of Their Equivalent in Hourly Wages.

If this measure has any significance, it should purport to show how long the working man must labor in each country in order to buy a supply of each drug. While this might be of some academic interest, it has nothing to do with the costs of producing, shipping, and selling drugs in a given market. But it does not even have anything to do with the working man's real wages in terms of drug purchasing power. Nothing, that is, unless the working man is a druggist. The prices shown are prices to the retailer, not the patient. Presumably it is easier to obtain data on prices to the druggist than to the consumer. But by choosing druggist's cost the effect is without doubt to understate Canadian prices relative to other world prices because of the comparatively much higher retail markup in Canada, which seems to average 100 per cent, as compared to 66 2/3 per cent even in the United States, and in Great Britain only 18 per cent plus a dispensing fee of about 17 pence. Hence the statistics show nothing concerning relative prices to the consumer, whether he is laborer or capitalist.

As the Consumers' Association of Canada has aptly pointed out in its brief to this Committee, PMAC seems to be endorsing the Marxist concept of the labor theory of value in this comparison. Even so, it would show only half of the picture. What is needed is also the number of labor hours necessary to produce a given drug in a particular country. If labor were the only factor of production, one would have

to neglect capital, land, management, and other possible classifications of productive factors. However, orthodox Marxists are willing to do just this, so PMAC is not innovating an entirely new economic theory. All PMAC needs to do is to compute the number of hours necessary to produce each drug in each country, subtract this from their figure on the number of labor hours expended in financing the comsumption of each drug, and the difference will represent the number of labor hours of "surplus value" extorted from the worker by the drug maker. Is this criticism to be taken seriously? It must, if PMAC's statistics are to be taken at face value.

As indicated in the test of the Alberta submission, the computation actually shows that prices are higher in those countries in which per capita income is higher. This is no doubt the case because consumers can afford to pay higher prices in countries in which incomes are greater.

The relationship between drug costs and per capita income cannot be ascertained precisely on the basis of information given in the PMAC brief, since the price indices computed therein are merely simple arithmetic averages of unweighted prices instead of having been weighted by the total expenditures of consumers in each country for each drug. As the Consumers Association of Canada Brief appropriately observes, this procedure "violates the central tenets of index number theory by taking as an index an unweighted average of drug prices." (7o). Still, if PMAC advocates the use of an unweighted index for computing the cost of drugs in terms of labor hours, it should have no objection to the use of an unweighted index for computing average money prices of drugs in the selected countries. If we compute the average price, in Canadian dollars, of the seventeen drugs listed by PMAC on pages 3 and 4 of Appendix F of its submission, we have a measure of the relative money costs, in terms of 1964 Canadian dollars, of the "average" drug purchased from this group of 17 drugs, in each of the eight countries. If we compare these average drug prices with average per

capita income (in 1964 Canadian dollars) in each of these countries, there is apparent a generally direct relationship between the height of drug prices (in constant 1964 Canadian dollar terms) and the height of per capita income (also converted to 1964 Canadian dollar equivalents, by use of the statistics on national income and population for 1964 as given in the United Nations Statistical Yearbook for 1966.) The relationship is given below:

	Average drug price	Per capita income, 1964
United States	$ 4.64	$ 3485
Canada	4.45	2502
France	3.59	1869
Germany (Federal Republic)	3.56	2145
Holland	3.73	1615
Sweden	3.28	2640
United Kingdom	3.03	1935
Italy	2.85	1116

It can be seen that prices are highest and lowest in the countries with highest and lowest per capita incomes, respectively. Between these extremes there is some variation, but only Sweden, with sixth highest average prices and second highest per capita income, is significantly out of line with the general relationship. (The co-efficient of Spearman Rank-Order Correlation is .500. Perfect correlation would be represented by a co-efficient of 1.00.) It is true that the computed averages are not entirely comparable in the cases of Italy, Sweden, France, Holland, and the United Kingdom, where price information is not given for all 17 of the drugs. But this criticism applies also to the PMAC presentation.

A slightly different way of making the comparison between drug prices in Canada and in other countries (which reduces, but does not eliminate the statistical shortcomings of the previous computation) is to take the price of each drug in each foreign country (expressed in Canadian dollars) and divide it by the Canadian price of the drug, expressing the price ratio as a decimal fraction. For each country the

average price ratio is then computed by taking the unweighted arithmetic average of the ratios for each of the drugs separately. The results of the computation show clearly that prices in Canada are higher than in any of the other countries except the United States:

	Ratio of drug prices in each country to drug prices in Canada	Index of foreign drug prices in terms of Canadian drug prices
United States	1.062	106.2
Canada	1.000	100.0
Germany (Federal Republic)	.840	84.0
Holland	.833	83.3
Italy	.770	77.0
Sweden	.767	76.7
France	.725	72.5
United Kingdom	.670	67.0

It is interesting to note that Professor P.C. Briant, in explaining the PMAC labor value computations before this Committee failed to defend in principle the labor-hours basis of the index, and betrayed implicit lack of confidence in the value of an unweighted index in responding to a criticism by Dr. Howe regarding the validity of the index. During the proceedings, Mr. Laidlaw, as counsel for the Committee, asked Dr. Briant the following question: ".....It seems to me that your hypothesis is...entirely wrong. If butazolidin reaches the consumer in the United Kingdom at a special price, it reaches the consumer in Canada at three times that price, what has the Canadian earning capacity to do with it?" Dr. Briant responded with the surprisingly critical statement, "I did not really start out with the hypothesis that this is the proper way to measure comparative costs." If this is the case, one wonders why the proper way to measure costs was not employed, and what precisely was the intention in presenting the data in the form chosen by PMAC. (The next statement by Professor Briant may have some bearing on this point, as he added: "I did start

out with the assumption that we are interested in maintaining a pharmaceutical manufacturing industry in this country....." (7p)

With regard to the relative value of weighted vs. unweighted indices, Dr. Briant implicitly revealed his preference in responding to a criticism of the PMAC data by Dr. Howe, who had presented a list of 58 drugs the retail prices of which were from three to twenty times as high in Canada as in the United Kingdom. Dr. Briant computed that, for the fifteen drugs (in the PMAC list of 17) which were actually sold in the U.K., comparative money prices to the consumer for the unweighted sum of "a basket of 15 of these drugs" (7q) were \$66.91 (in Canadian dollars) in the United Kingdom and \$111.40 in Canada, showing that prices were 66.5 per cent higher in Canada. (For what it is worth, the equivalent labor hours were computed by Dr. Briant to be 15.5 per cent higher in the United Kingdom.) For the 58 drugs in Dr. Howe's list, the unweighted sum total cost of buying one dosage-pricing unit of each drug at the consumer price level was \$130.05 in the United Kingdom and \$599.72 in Canada. Hence prices in Canada were 361.1 per cent higher than those in England. Again, for what it may be worth, Dr. Briant computed that the equivalent labor hours required to purchase the drugs was only 4.17 per cent as great in the United Kingdom as in Canada.

Dr. Briant then found it "statistically reasonable" to combine the 17 drugs in the original PMAC list with the 58 drugs in Dr. Howe's list to obtain an index for all 75 drugs, by "weighting the index relatives by the relative market shares" of each drug. (7r) It is not explained why it is statistically reasonable in one context to use a weighted index, while in all other contexts the use of unweighted indices is apparently regarded as requiring no particular justification. Interestingly enough, the introduction of market share weights makes a substantial difference. Since Dr. Briant had previously been comparing an unweighted index of 15 drugs with an equally unweighted index of 58 other drugs, one would suppose that mere

consistency would require the computation of an unweighted index for the entire group taken together. If this procedure were followed, it would appear that money costs in Canada would be 261 per cent higher than in the United Kingdom, while, if relevant, even equivalent labor hours costs would be only 54 per cent as great in the United Kingdom as in Canada. But if one adopts the weighting procedure advocated (in this context only) by Dr. Briant, relative money costs are only 151 per cent greater in Canada and equivalent labor hours are 91 per cent as great in the United Kingdom as in Canada. It is this last comparison which Dr. Briant stresses--that 91 per cent is only "somewhat lower" than the Canadian standard of 100 per cent. What deserves emphasis, however, is that if timely adoption of the weighting procedure had not been resorted to at this point, the "blended" index of 75 drugs would still have shown equivalent labor hours to purchase drugs in the United Kingdom as only about 54 per cent as great as in Canada.

The point is not that it is an error to employ weights in the "blended" index, but that it is erroneous to use unweighted indices in all other contexts. Moreover, the precise effect of either weighted or unweighted indices on the computation of equivalent labor hours to purchase drugs is irrelevant since the magnitude being measured is strictly irrelevant. At best, a lower ratio for Canada than for other countries would indicate nothing more than the simple fact that Canadian labor is relatively more productive, per hour, than labor in other countries, such that Canadian wages permit workers to buy given amounts of any particular good with fewer labor hours expended.[1] But the extent to which Canadians are able to translate their relatively greater productivity per labor hour into a greater command over goods

---

1

Since one of the principal determinantes of wage rates is the amount of capital investment per worker employed, this may indicate indirectly the relatively more capital-intensive methods of production prevalent in Canada.

and services on the market depends upon the degree to which the products of different industries are priced competitvely (i.e., relatively close to production costs) or monopolistically in different countries. It might be of some limited interest to compute weighted indices of relative labor hours required to purchase a variety of different goods in different countries, produced by competitive as well as monopolistic industries, comparing drugs with raw materials durable and non-durable consumer goods, foodstuffs, and the like.

Breakdown of the Prescription Dollar

In Section 2 of the PMAC Submission it is asserted that the manufacturer's portion of the prescription dollar is only 37.5 per cent. This would appear to be understated, but the true share is a matter of conjecture. PMAC refers to the 1964 annual survey of prescription prices conducted by the Canadian Pharmaceutical Association which stated that the average price of a prescription was $3.47, and the cost of the ingredients to the pharmacist was $1.73, or exactly 50 per cent of the price. PMAC then concludes, not too explicitly "when additional allowances are made for wholesale distribution and federal sales tax the manufacturer's portion of the average prescription is $1.30 or 37.5 cents of the average prescription dollar." (6e). Apparently the computation was made as follows: from $1.75 deduct the wholesaler's markup of 20 per cent over his invoice cost, which would amount to 1/6 of the price to the druggist, or 29 cents. This leaves $1.44 as the price to the wholesaler, which includes 11 per cent sales tax, the deduction of which would require that $1.44 be reduced by 11/111, or 14 cents, yielding PMAC's $1.30 net to the manufacturer.

The difficulty with this procedure is that it assumes that all drugs sold pass through the hands of wholesalers. To the extent that manufacturers sell direct to various classes of buyers, they bypass wholesalers. As manufacturers they therefore perform also the wholesaler's function on these sales, incurring extra costs, but also

receiving an extra share of the sales dollar. The costs incurred in performing wholesaling functions appear to be included in the table on page 2.2, "Manufacturer's portion of the prescription dollar" presumably under the heading "distributing and warehousing costs," but the additional revenue from selling the drugs at the higher price obtained by selling direct rather than through wholesalers is omitted. Hence the manufacturer's share of the consumer's prescription dollar is understated. What is the approximate magnitude of the understatement? This would depend upon the relative share of sales made direct to retailers (at an average discount of presumably 40 per cent below suggested list price to consumers) and the share of sales made to wholesaler (at a discount of presumably 50 per cent below suggested list price to consumers.) The only information we have is that volunteered by Dr. Briant (7s) to the effect that in 1964 sales by PMAC members were divided up as follows: $23.5 million direct to retailers; $49.9 million to wholesalers; $27 million to hospitals; $3.2 million to government buyers, and $1.15 million in export sales. Hence only about 47.6 per cent of total sales were made through wholesalers. If we then assume that manufacturers realized 40 per cent of suggested consumer list price on roughly 50 per cent of their sales, and 50 per cent of list on the other half of their total sales, the manufacturer's share in the prescription dollar should be increased by one-half of the 29 cents deducted to allow for the wholesaler's margin, or 14.5 cents. This would increase the drug firm's share of the sales dollar to $1.445, or about 41.6 cents in the sales dollar, indicating an understatement of about 11.1 per cent in the PMAC Submission.

The validity of this computation depends upon the accuracy of the figures quoted by Dr. Briant and the representativeness of the Canadian Pharmaceutical Association survey. The consistency of the latter survey with the Submission of the Canadian Pharmaceutical Association before this Committee in June, 1966, is not established,

since in the latter presentation it was asserted that 62 cents, rather than 50, in the consumer's drug store dollar were accounted for by payments to drug manufacturers and distributors. (The discrepancy between 50 and 62 cents remains unexplained, since the elucidation in paragraphs 7.6 and 7.7 of the CPA Submission is less than enlightening.) (7t). Other fragmentary evidence exists to suggest that both the estimates of 37.5 per cent and 41.6 per cent of the consumer's prescription dollar may be on the low side. For example, Lederle in the United States in 1958 submitted that the manufacturer received 51 per cent of the prescription dollar. (3b). While the comparable figure for Canada would probably be lower because of the sales tax and the higher markup imposed by the druggist, it is still surprising to note the difference of from 10 to 13 percentage points in the drug maker's share of the consumer dollar.

The Reasons for Multiple Pricing

On pages 5.4 and 5.5 of the PMAC Submission some of the factors responsible for price discrimination between retail pharmacy, hospital formulary, and government bid markets are adumbrated, but not analyzed, in a section entitled "The Reasons for Multiple Pricing." Two valid reasons for price differences are stated: the sales tax exemption to hospitals and quantity discounts for large purchases, but the quantitative importance of each of these factors, taken by itself, is not indicated. It is also suggested that firms wish to have their products used in hospitals in order to allow physicians to become acquainted with them, but this consideration would seem at best a very minor factor in view of the comprehensiveness of drug industry sales promotion efforts along other lines.

The last mentioned factor is "The competitive situation." Interestingly, emphasis is not upon competition among major brand name firms, but with the producer of the "so-called generic equivalent." Also, the reference to competition is limited to hospital and government markets: "the original manufacturer has to decide whether to abandon the hospital or government market, or to reduce his price to a

level which will meet" that of a generic producer. The paragraph concludes: "In effect, he is forced to compete for business, often based on quite general specifications, against naturally cheaper, and it may well be, inferior, products. He will do this to maintain an important market or to protect the reputation of his product; in the event of the failure of a so-called equivalent formulation doctors may well blame the drug itself." (6f).

This paragraph is of interest to the student of competition in the drug industry for several reasons:

(1) It betrays the extent to which major drug firms consider themselves above the necessity of competing in the market on a price basis. In a competitive market, firms naturally expect to be "forced to compete for business" and if the products of competitors are "naturally cheaper," the decision of "whether to abandon" a given market will be made by the price-conscious buyers themselves, not the higher-cost seller. Furthermore, the art of competing is seen in terms of arriving at price levels "which will meet," not undercut, those of rivals.

(2) It also conveys the frame of mind of major sellers insofar as they do not expect to have to compete on a price basis except with generic firms in hospital and government markets. One wishes the PMAC Submission would explain why "the competitive situation" is limited to these areas. Why is the possibility not mentioned that major firms might not find a competitive situation developing between themselves in making sales to pharmacies, hospitals, and government agencies? Why is the further possibility not mentioned that major firms might have to compete on a price basis against generic firms in the pharmacy market? Is it because under present market circumstances these possibilities are too remote to warrant mention?

(3) It illustrates the propensity of the brand name firm to indulge in blanket disparagement of the quality of the products of

generic name sellers, and the skillful manner in which such a propensity can be exercised. For example, the following negative impressions of generic products are conveyed in this paragraph:

(a) The generic seller is by implication an "unfair" competitor because he has managed to avoid the now "sunk" costs of research and marketing. Actually it is a sign of economic efficiency to operate a low cost levels, and it is indicative of poor business judgment to allow past or "sunk" costs to influence one's present pricing policies, particularly in a competitive market.

(b) By referring to the "so-called generic equivalent" and "A so-called equivalent formulation" and to "naturally cheaper, and it may well be, inferior, products" PMAC is by implication disparaging any and all generic drugs without sufficient justification.

(c) By referring to the brand name version of a drug as "the drug itself" PMAC is implying that there must be a difference in kind between generic name and brand name drugs, which is also without justification.

Recommendations by PMAC

Several of the recommendations of PMAC are clearly in the public interest, if adopted as part of a more comprehensive reform and adequately implemented. The abolition of the federal sales tax on drugs is an excellent recommendation, but it does not necessarily follow that consumer prices will be reduced accordingly unless other reforms are also taken, as explained in the body of the Alberta submission.

The recommendation that an independent source of drug information for doctors and pharmacists be established is also worthy of support, provided that the source of this information remains truly independent of the drug industry. The further recommendation that more comprehensive statistics on drug costs, prices, and expenditures be collected is also praiseworthy, provided that the statistics collected and published are in all respects accurate and unbiassed. The same is

true regarding the provision to physicians of reliable data on drug therapy costs.

On the other hand, it is hard to take seriously any reference to a program for voluntary drug price restraint. And the suggestion that the problem of drug costs is not high prices, but low incomes, should be vigorously repudiated. These are two problems, not one. Drug prices are high to the affluent as well as to the indigent because they are well in excess of production cost. The problem of high drug prices should be attacked as such, just as the problem of low incomes should be approached as an entirely separate problem, whether or not critically low incomes happen to be received by the healthy or the afflicted. PMAC recommends a wider availability of programs for drug insurance prepayment, which would "provide an effective vehicle through which government can help those who need assistance." (6g). This sounds plausible, but unless there is some control over drug prices, private insurance programs and expanded government aid will simply increase the effective demand for drugs without in any way exerting a disciplining influence over prices. The result will be increased drug prices, sales and profits.

In fact, private and public drug insurance plans and public welfare and assistance programs may prove to be impediments rather than useful expedients in the solution of the problem of high drug prices--unless the insuring agencies and the public organizations providing assistance can secure and exert bargaining power in order to discipline drug prices and charges. A common feature in most legislation of the "medicare" variety is the provision of funds which will increase effective money demand for health services without at the same time providing adequately for an increase in the supply of these services, or even for securing a more efficiently produced and reasonably priced provision of the existing supply. It is certain that if demand increases while supply remains substantially constant, prices will

increase. This is all the more true if suppliers are not competitive and look upon the provision of more funds for health care as providing them with a guaranteed increase in their market. Hence public policy should take steps to stimulate new competition in the drug market at the same time that it undertakes measures for increasing the availability of public funds for drug care for the indigent.

APPENDIX C

COMMENTS ON THE SUBMISSION OF THE PATENT AND TRADEMARK INSTITUTE OF CANADA

In this Submission, the Patent and Trademark Institute of Canada recommends that the legal privileges afforded drug patent holders be greatly strengthened by the repeal of Section 41 of the Patent Act, and by drafting new patent legislation "defining objectively the obligations to the public of the holder of a drug patent, and the basis upon which such drug patent holder is to be remunerated for the use of his invention upon grant of a compulsory license." (7u). This would make it possible for the obligations to be narrowly defined, and even for the statutory requirement of royalties high enough to deprive the Canadian public of the benefit of genuine price competition between patent holder and compulsory licensee. In contrast, present legislation serves the interest of Canadian consumers by specifying that compulsory licenses on drug patents shall be granted unless the Commissioner sees good reason to the contrary, and by awarding royalties at rates permitting the supplying of the public at the lowest possible price consistent with rewarding the inventor. Furthermore, in this submission it is recommended that no changes be made in the Trade Marks Act which would put drug trademarks on a different footing than other trademarks. Since no recommendations are made as to the proper method of reforming drug trademarks without introducing some distinction in treatment between drugs and other trademarked goods, it is to be inferred that no change in the Trade Marks Act is to be desired.

One is reminded of the Submission of the American Bar Association before the Kefauver Subcommittee in the United States, in which every patent reform provision contemplated in the proposed Drug Industry Antitrust Act was rejected as undesirable--not from the point of view of public policy, but from an over-riding concern with the preservation of the body of patent law in the United States. It would be unfair, and an over simplification, to characterize the attitude of

patent attorneys toward patent reform as an instinctively conservative reaction in the direction of protecting obvious vested interests in the subject matter of their profession. The roots of their opposition are more ramified and more complex. Still, it is doubtful if the Patent and Trademark Institute is qualified to deal with problems of patent reform from a purely objective and disinterested perspective.

Nor is the Institute qualified to deal with the economics of the patent system as it affects competition in the drug market. Mr. Smart, in speaking for the Institute before this Committee, was explicit on this point: "We, as members of the Institute to which we belong, are not concerned with and are not knowledgeable on the economic aspects of the subject." (7w). The Submission itself, furthermore, is more than modest in claiming that it comes to grips with the major problems of drug costs and prices with which this Committee is concerned. In the introduction to the Institute's brief it is stated that "While we do not deal directly with drug costs and prices we feel that in relation to our object of promoting clear legislation which is easy to understand and administer we are, in relation to patented and trade marked drugs at least, dealing with a factor of cost...Thus, while our submission is mainly directed to the state of the law, it is not wholly without relevance to the subject of costs and prices." (7x). The more important object would seem to be to promote legislation which is in the public interest; clarity, although desirable, should be a secondary consideration. (For that matter, if the minimization of patent litigation costs and uncertainties is of paramount importance, it would seem that this could be done most effectively by abolishing drug patents.)

As was pointed out at some length in the report of the Ilsley Commission, the system of patent law as a whole has many critics and is subjected to many criticisms. Most of these criticisms become more pointed when directed to drug patents. Some of these criticisms

seem particularly compelling to economists, who are professionally concerned with promoting competition and controlling monopolistic forces.[1] While most of the countries in the world grant process patents on drugs, the great majority of them regard the granting of product patents on drugs as contrary to humane public policy and hence insupportable. Of those countries granting both product and process patents, only Panama, Belgium, and the United States have been sufficiently indifferent to the interests of the consumers as to make no provision for compulsory licensing of food and drug patents under appropriate circumstances. The basis in public policy for denying product patents is the principle that no one should be entrusted with absolute monopoly power over products essential for human health and life. In chemical industries, however, owing to the ease with which

---

1

Even an economist who has been retained by counsel for a trade association of drug makers may not be able to resist expressing his reservations concerning the suitability or expediency of existing patent law. Prof. E.V. Rostow, Dean of Yale University Law School, when appearing before the Kefauver Subcommittee on behalf of the Pharmaceutical Manufacturers Association of the United States, stated: "I recall a meeting of a committee of the American Law Institute where Judge Learned Hand remarked that one of the strongest impressions he had of his many years on the federal bench was that the patent law had some fundamental defects. His view is supported by a good deal of evidence, including the studies of scholars, and some useful papers prepared for this and other congressional committees. We need much more information, and much more research and study about the conditions of creativity of American science, before we can be sure that our patent law, and other arrangements for encouraging and rewarding creativity in science, are in fact adequate and effective. (9i).

process patents could be by-passed through the devising of new (and hopefully improved) processes, it was felt to be in the public interest to allow drug process patents and hence to improve the prospects for rapid technical progress. As L.J. Robbins has observed, "The limitation of protection for chemical products in general as well as pharmaceutical products in particular, to process claims, is essentially a continental European conception, and is tied up with social thinking in the 19th century during the industrial revolution. It became a matter of practically unassailable dogma that if the public is to receive the benefit of new chemical or pharmaceutical products at a reasonable price and in amounts sufficient to meet the demand, that this could only be accomplished by restricting the inventor to his process, so that others will be encouraged to invent new and improved processes which will make the product cheaper and available in greater quantities." (24). With these considerations in mind one can better evaluate the positions taken by the Institute regarding drug patents and the Patent Act.

It is contended that abolition of drug patents would occasion at least three difficulties. One of these consists in the difficulty of identifying a drug patent. This is apparently a very good point, and if it is decided to abolish drug patents, great care should be taken in drafting the law to insure that drug patents are very inclusively defined. It is in such an area as this, rather than in the field of establishing public policy goals, that the assistance of the Institute in drafting reform legislation would be invaluable. A second difficulty is said to reside in the necessity of making patent abolition apply to drugs patents already granted but not yet expired. In itself, this should occasion no real difficulty; the Institute seems to be concerned, rather, with possible inequities rather than technical legal difficulties. The sentence, "The alternative, that of making the legislation retroactive, would give rise to difficulty of compensation to the patent holders and applicants whose rights were legislated out

of existence posing almost insurmountable problems of assessment and valuation or the imposition of what would effectively be legislative confiscation without compensation." (7y) seems to raise some problems which are more apparent than real. In an economic sense, patents confer privileges, not rights. If the social value of the process patent device in drugs is to stimulate more rapid invention, then the virtue of the patent privilege resides not in the reward which it gives to the possessor of an existing patent, but in the incentive which it gives others to by-pass the patent. In other words, the patent system should be regarded as designed to improve technology not so much because of existing patent protection, as in spite of it. The abolition of drug patents would presuppose a conviction upon the part of the public that drug process patents were not an expedient means of promoting such technical progress; hence the privilege which the patent conferred upon past possessors was undeserved. Under these circumstances it is an open question whether abstract equity would not be better served by seeking to recover damages from previous patent holders than by awarding compensation to those whose monopoly privileges have been terminated earlier than expected. In the United States it is an established principle of antitrust law that in the exercise of the regulation of prices charged by monopolists such prices may be lowered without entitling the monopolist to compensation because the reduction in price lowered the discounted future value of prospective monopoly p profits and hence reduced the market value of the monopolistic firm as an entity. It has been held that the expectation of the undisturbed exercise of monopoly pricing powers and the capitalization of anticipated future monopoly profits therefrom does not create a property right to compensation when such market values are destroyed by price regulation. The same principle should in all fairness be applied to patent monopolists, particularly if and when the time arrives when it is decided that drug patents are contrary to the public interest.

A third objection is more serious, namely, the threat of international retaliation. This is the most important reason why

licenses to import may be preferable to the complete abolition of drug patents. The Institute asks this question: "Since the proposal does have international implications it is fair to ask how such measure would affect Canada's image abroad." (7z). It is likely that Canada's "image" will be enhanced in the minds of those throughout the world who feel that it is only just to protect the drug consumer against economic exploitation.

In recommending the abolition of section 41 of the Patent Act, the Institute advances a number of reasons for its position. First, it is alleged that since 1923 the science of chemistry has advanced so greatly that the "philosophy" behind section 41 is no longer valid. Second, it is submitted that the advance of science has rendered the words of the statute no longer clear and precise, but instead subject to a variety of plausible interpretations. The point of the illustrations given in support of the second contention is that the current interpretation of section 41 (1) by the courts makes it "booby-trapped with special requirements for validity which are frequently impossible to meet." (7aa). In support of the first contention some rather more substantive issues are raised. It is alleged that at the time section 41 was passed, the promise of chemistry was envisaged in terms of process improvements rather than the devising of wholly new products. Since that time, it is argued, synthetic chemistry has become more important, and compounds not occurring in nature can be routinely synthesized, while diminishing returns have set in for process innovations, such that a fundamentally new chemical method is said to be extremely rare. Reference is made to a decision of the Supreme Court of Canada in which it was held that the inventive virtue for a given drug resided in the discovery of the useful properties of the product rather than in the method of producing it. The conclusion is that what was in 1923 "regarded as the inventive merit, namely the process, is out of place in a later day and age which regards the discovered intrinsic properties of the product as the seat of inventive merit." (7aa). This discussion

raises the question that under these circumstances neither the product *per se* not the process is regarded as constituting invention. This suggests the possibility that drug developments may become fundamentally unpatentable under conventional patent laws. This brings to mind one of the major criticisms of patent law--that it rewards certain types of "inventions" quite lavishing and cannot be adapted to rewarding other types of productive creativeness. Judged from this perspective, some of the complaints against the obsolescence of the "wording" of section 41 (1) of the Patent Act may be interpreted more broadly as implying that increasing emphasis on proof of the useful properties of a newly discovered compound may make drug patent protection of the conventional type practically unobtainable regardless of ingenuity in wording a statute.

In response to these observations, it may be argued that the purpose of section 41 is to protect the consumer against exploitation by drug patent holders. If the science of chemistry has advanced so greatly since 1923, the "philosophy" behind section 41 referred to by the Institute may be more valid than ever, particularly if the collective economic power of the major drug firms in the world drug industry (but not necessarily of individual firms taken singly) has greatly increased as a result. Secondly, it may then be desirable that judicial interpretation of section 41 (1) has made it increasingly difficult to secure a drug patent, since the inventive merit in what it has been considered is in the public interest to make patentable--the process innovation--has allegedly decreased. And it is by no means certain that it is in the public interest to make what is currently increasingly regarded as the inventive merit--the discovery of the useful properties of a compound--routinely patentable.

Some very useful observations are made by the Institute in regard to improving the patent law to make more adequate provision for the public interest in respect to food and drugs. Since section 41 (1) prohibits the patenting of new compounds only when produced by chemical processes and intended for food or medicine, it prevents the possibility

of compulsory licensing of foods or drugs not made by chemical processes. Further, it does not allow for the compulsory licensing of patents on products or processes not originally intended for food or durg applications but subsequently discovered to have such applications before the period of patent protection has expired. The aid of the Institute would be invaluable in this context as well, in drafting legislation which would provide for compulsory licenses in each of these instances.

The Institute expresses the opinion that the repeal of section 41 (1) would serve a useful purpose in encouraging technological advance in drugs; beyond that, it is asserted that the importance of the patent incentive "is, if anything, greater in relation to the medical arts than it is in relation to the other useful scientific arts." (7bb). Any number of physicians and medical technicians who have devised diagnostic aids or surgical inventions and innovations and have been above patenting them might well take exception to this statement.[1]

The language in which the Institute denounces section 41 (3) constitutes a recognizable rhetorical landmark in these proceedings: "In short, the intent of this section as interpreted by the courts is to take from the patentee and give to anyone who make application the right to, for practical purposes, a virtual free ride on the patentee's coat-tails unless the Commissioner of Patents sees some as yet undefined "reason to the contrary."" (7cc). If patent holders actually do feel thus thwarted it is perhaps an indication that section 41 (3) is being interpreted in accordance with the intent of protecting drug consumers by promoting competition. The best expression of the contrary attitude--that the world owes the drug patent holder a living--is to be found in

---

1

The best recent example of this is the invention of the "mechanical heart", devised by a team of researchers from Baylor Medical College in Houston, Texas and a local engineering school. Dr. Michael DeBakey spoke for the entire group when he characterized as unthinkable the notion of obtaining a patent on this life-saving device.

Cyanamid's unusually colorful Submission to this Committee. A parable is developed at some length in which the virtues of the "Innovator" are proclaimed in bold contrast to the parasitic character of the "Copier." Space is lacking in which to supply an economic interpretation of this ethical parable. To an economist it is obvious that the word "innovator" should be replaced by "monopolist" and the word "copier" should be replaced by "competitor." This may be the most concise way in which to deflate the atmosphere of moral indignation created, and place things in a true economic perspective.[1] (For example, the Copier is castigated since he "obtains his bulk active ingredient on the world market at the lowest possible price" as if there were some more logical way of doing business efficiently.) (7dd). The Hoffman--La Roche Brief engages in the same sort of earnest discussion of "originators" and "copiers" and contains many revealing remarks (such as "competition, which is meaningless if it is not equal" (7ff) which suggest that monopoly privilege has become such a way of life that the firm is really disoriented to the realities of a competitive market.

The Institute rejects the recommendation of the Hall Commission that section 20 of the Trade Marks Act be amended to eliminate the possibility of infringement proceedings when goods bearing the same trademark but produced by domestic and foreign related companies, are sold in competition in the domestic market. The grounds for rejecting this recommendation are not entirely clear. On the one hand it is urged that the public interest in the integrity of trade marks is great, and

---

1

During the Proceedings before this Committee, Mr. Bertrand of Cyanamid was asked by Mr. O'Keefe: "Is your firm always an innovator and never a copier?" The reply was in the affirmative. (7ee). But outside observers might not be so charitable. C. E. Silberman has observed that Cyanamid's Lederle division is so versatile that it is not limited to innovating wholly new departures in drugs, but can also mount a molecular-manipulation effort to keep abreast of the developments of others. This is perhaps not "copying" in the narrow sense of the Cyanamid parable, but it is not fundamental innovation either. (13)

probably greatest in the area of drugs. On the other hand, the nature of this public interest is not satisfactorily specified. It is emphasized that a trademark is a badge of origin for a particular good, certifying its quality and the conditions of its manufacturer. This can only be true in a very general sense; otherwise different trademarks would have to be applied to goods produced in different plants, in different grades or qualities, and by different methods, even if the same firm were the producer. Mr. Smart came closer to identifying the commercial value of the trademark (as possibly distinct from the differential use value of the trademarked product to the consumer relative to that of another product bearing another trademark) when he stated: "A trade mark is something that has validity because of something that is in the minds of the public in relation to it." (7gg). Hence the value of a trademark to a firm is created by successful advertising and sales promotion strategies which differentiate the trademarked product from the products of other sellers. The precise value of the trademark to the buyer, however, is difficult to determine.

As the law now stands, it appears that trademarks do not necessarily function as a badge of origin--not only with regard to plant of manufacture, but even with regard to country of manufacture. It appears that if a Canadian firm does not own the trademark registration but merely uses the mark as a registered user, the sale of goods bearing the same trademark, but produced abroad rather than in Canada, would not consitutue trademark infringement. Furthermore, the Institute observes that any company which found its Canadian subsidiary was being injured by importation of identically trademarked wares from related companies abroad would thereupon change the trademark used by the Canadian firm. This is surely a possibility, but it may occasion some cost, particularly in the case of a Canadian subsidiary of a United States firm where the trademarked name of the firm's product is well-known in Canada through intensive advertising in North American media read and heard in both countries. In such a case, changing the name

and trademark of the Canadian product would cost the subsidiary the accumulated "good will" associated with the widely known and persistently advertised brand name. However, it is surely logical that such a step be taken, if the virtue of the trademark resides in its being a unique badge of origin.

The Institue is also of the opinion that reform is unnecessary since there is nothing in the Trade Marks Act to prevent a Canadian importer from purchasing abroad finished drugs from a related company of a Canadian firm and then selling them in Canada under the importer's own label. However, there is nothing in the Trade Marks Act which compels the related company to sell to the Canadian importer for repackaging purposes--this might not be consistent with the foreign affiliate's view of the fitness of things. More importantly, even if the importer obtained the very highest quality finished drugs from the foreign trade mark holder, if he sold them under his own (presumably less well known) brand name, he would be likely to sell less and to be forced to charge a lower price because he would not be selling them under the foreign firm's widely advertised brand name.

Finally, the Institute suggests that there is no need for reform in the Trade Marks Act because section 30 of the Combines Investigation Act may be invoked in cases of the abuse of trademarks. It is hard to take this recommendation seriously since the expense, delays, and general cumbersomeness and uncertainty of such proceedings would make this remedy in every sense of the phrase a last resort.

Appendix D

DRUG PRICES IN ALBERTA ANTIBIOTICS

1 Generic Name	2 Brand Name	3 Manufacturer's Cost	4 List Price	5 Price to Retail Pharmacist	6 Price to Wholesaler	7 Price to University Hospital Edmonton	8 Price to Alberta Department of Health
Erythromycin 250 mg.	Erythrocin Abbott	$4.96 to 5.02 per 100 g.b. 177(1)	$40.55/100	$27.03/100		$18.35/100	
	Ilosone Lilly		$40.55/100	$24.33/100		$14.50/100	
Novabiocin 250 mg.	Albamycin Upjohn	$14.64/100	$50.50/100	$30.30/100		$25.60/100	
	Cathomycin Merck	$6.91/100 g.b. 181(2)	$50.50/100	$30.30/100		$22.75/100	
Tetracycline 250 mg.	Achromycin Lederle	$644.15 kg g.b. 169 $340.00 kg (2)	$540/16 $29.50/100	$17.70/100		$13.05/100	
	Tetracyn Pfizer	$156.71 to $525.36 kg g.b. 169	$30.00/100	$21.99/100		$16.20/100	
	Tetrex Bristol	$140.00 kg or $3.50/100 g.b. 169	$30.00/100	$18.00/100		$16.22/100	
	Muracine Nadeau	N.A.	$32.00/100	$16.00/100		$4.60/100	
	Canada Pharmacil					$30.30/M	

(1) Green Book: Department of Justice, Ottawa, 1961, Report on Manufacture, Distribution and Sale of Drugs by Director of Investigation and Research, Combines Investigation Act.

(2) The theoretical cost of the drug in 100, 250 mg. capsules at Merck's buying price (i.e. $276.50 per kilogram) would be $6.91.

(3) Cost of 88% crude aureomycin refined and chemically converted to Achromycin. See R.T.P.C. proceedings Vol. 15 p.1651

(4) See also chart reproduced in Submission of Alberta to Hall Commission showing Upjohn's and Bristol's costs and selling prices for tetracycline capsules.

(5) Ditto

ANTIBIOTICS

Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
Tetracycline 250 mg	Empire Generic	NA	$20.60/100	$12.36/100			
	Gilbert Generic	NA	$6.00/100	$4.50/100	$3.75/100	$3.96/100	
Chloro-tetracycline 250 mg.	Aureomycin Lederle	$476.51 kg	$5.40/16 $29.50/100	$3.24/16 $17.70/100		$15.95/100	
Chloram-phenicol 250 mg gb 168	Chloromycetin Parke,Davis	$90.00 kg or 2¼¢ each or $2.25/100	$39.40/100	$23.60/100		$12.50/100	
	Enicol Intra		$39.40/100	$23.82/100		$9.00/100	
	Mycinol Horner		$39.40/100			$9.50/100	
	Empire Generic		$15.70/100				
Cycloserine 250 mg	D-Cycloserine Hoffman, LaRoche	$14.76/100 g.b. 178	$49.10/100	$29.46/100		$21.36/100	
	Seromycin Lilly	g.b. 178 $5.96/40 $71.93/500	$19.50/40 $233.34/500	$11.70/40 $140.00/500			

CORTICOSTEROIDS

Generic Name	Brand Name	Manufacturer's Cost (1)	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
Prednisone 5 mg	Meticorten Schering		$7.10/30 $22.70/100 $109.00/500	$13.62/100		$9.25/1000	
	Prednisone British Drug Houses		$4.20/100 $20.00/500	$2.52/100		$6.75/1000	
	Delta Cortef Upjohn		$3.00/30 $22.70/100	$16.34			
	Paracort Parke, Davis		$4.20/100			$1.20/100	
	Colisone Frosst		$4.20/100	$2.80/100		$6.95/1000	
	Prednisone Intra		$7.20 ? $4.20/100	$4.50/100 ?		$1.33/100	
	Prednisone Empire		$4.00/100 $18.00/500				
	Prednisone Gilbert		$11.00/500	$8.80/500		$7.74/500	
	Prednisone Bell-Craig		$3.50/100 $13.50/500 $23.50/1000			$2.10/100 $8.10/500 $14.10/1000	

(1) Manufacturer's Cost is left blank because the Statement of Material Collected by the Director of Investigation and Research, Combines Investigation Act, does not cover Corticosteroids.

The United States Senate Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary (the Kefauver Committee) fully investigated Corticosteroids and at page 17 of its Report of May 8, 1961 the following statement is made:

" On a per tablet basis, the consumer using either prednisone or prednisolone bearing the brand name of one of the major pharmaceutical firms will pay approximately 30 cents for a pill which is sold to the druggist for some 18 cents and which can be produced for 1.5 cents or less. An arthritic patient will frequently remain for long periods on a dosage of about 100 of the 5-milligram tablets a month; thus he pays $30 a month for his medicine, for which his druggist paid around $18 but which cost around $1.50 to produce."

CORTICOSTEROIDS

Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
Prednisolone 5 mg	Meticostelone Schering	$1.57/100 (1)	$22.70/100 $109.00/500	$13.62/100		$10.00/500	
	Generic Bell-Craig		$3.67/100			$2.20/100	
	Generic Empire		$6.00/100 $27.50/500				
	Generic Gilbert		$11.50/500	$9.20/500		$8.09/500	
Triamcinolone 4 mg	Aristocort Lederle		$38.39/100	$23.00/100		$17.27/100	$17.27/100
	Kenacort Squibb		$38.40/100	$25.60/100		$18.65/100	
Dexamethasone 0.75 mg	Decadron Merck		$29.80/100	$17.88/100		$14.50/100	
	Generic Gilbert		$43.00/500	$34.40/500		$30.72/500	
	Generic Empire		$12.50/100 $57.00/500				
	Deronil Schering		$29.80/100 $140.00/500			$14.50/100 $44.50/500	

(1) Green Book p51: "No detailed information was obtained about cortisone or any related product. However, for comparative purposes, it may be noted that evidence before the recent senate committee in the United States was to the effect that, for Schering's prednisolone sold under the name meticortelone, the cost of manufacturing 100 tablets (five mg.) was $1.57. The selling price to a retail druggist was $17.90 and the suggested retail price was $29.83. The list or suggested selling price of the same tablets in Canada is $33.13." Note: Schering's present list price is $22.70/100.

CORTICOSTEROIDS

Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
Methyl-prednisolone 4 mg	Medrol Upjohn		$29.00/100	$17.40		$15.66/100	

TRANQUILLIZERS

Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
Promazine 25 mg	Sparine Wyeth	$0.0950/100 g.b. 198	$5.25/50 $45.00/500	$4.37/100	$3.71/100	$3.03/100	$21.00/1000
	Intrazine Intra	$0.0950/100 g.b. 198	$6.50/100			$1.83/1000	$19.50/1000
	Pro-Tran Mowatt & Moore	$0.0950/100	$4.75/50	$2.85/50	$2.42/50	$0.86/100	$8.58/1000
	Generic Empire		$1.50/100 $4.50/500				
	Generic Bell-Craig		$1.60/100 $5.00/500			$5.70/1000	
	Generic Gilbert		$4.00/500	$3.20/500		$2.81/500	
Chlor-promazine 25 mg	Largactil Ponlenc	$53.00 kg or $0.133/100 g.b. 186	$8.90/100 $38.30/500 $68.00/1000	$5.34/100	$4.54/100		$11.00/1000
50 mg	"	$0.265/100	$12.80/100 $55.30/500			$2.54/100	$20.00/1000
25 mg	Generic - Empire		$16.00/500				
50 mg	Generic - Empire		$6.70/100 $28.00/500				$3.00/1000

TRANQUILLIZERS

Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
Chlor-promazine 25 mg	Generic Bell-Craig		$2.09/100 $22.00/500 $40.00/1000			$ .10/1000	
50 mg	Generic Bell-Craig		$2.70/100 $11.00/500 $21.00/1000			$12.60/1000	
25 mg	Generic Gilbert		$6.60/500	$5.28/500			
50 mg	Generic Gilbert		$2.35/100 $10.00/500	$1.88/100 $8.00/500		$7.04/500	
Perphenazine 2 mg	Trilafon Schering	$5.10/1000 g.b. 194	$4.30/50 $8.60/100 $37.90/500			$2.32/100 $20.49/500	$19.85/1000
Trifluo-perazine 1 mg	Stelazine SKF	$1.15/1000 g.b. 201	$4.75/50	$2.85/50 $25.80/500		$4.65/100	2 mg. $32.00/1000 5 mg. $43.20
	Triflurin Paul Maney		$3.80/50			$1.70/100	
	Triperazine Gilbert		$3.50/100	$2.80/100		$2.46/100	
Hydoxyline 10 mg	Atarax Pfizer	$.043/100 g.b. 190	$6.16/100 $27.55/500	$3.70/100		$3.00/100	
25 mg	Atarax Pfizer		$11.00/100 $49.70/500			$6.72/100	$44.78/1000

TRANQUILLIZERS

Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
Tranyl-Cypromine 10 mg	Parnate SKF		$4.25/50	$2.55/50		$4.58/100	$30.00/1000
Thiori-dazine 100 mg	Mellaril Sandoz	$33.40/1000 g.b. 201	$12.50/50 $100.00/500			$85.50/1000	$65.80/1000
Triflu-promazine HCl 25 mg	Vesprin Squibb	$11.39/1000 g.b. 201	$13.50/100	$8.10/100		$7.36/100	$41.00/1000
Phenelzine Dihydrogen Sulphate 15 mg	Nardil Warner - Chilcott		$8.00/100 $38.00/500 $80.00/1000	$5.05/100 $48.00/1000	$4.08/100 $40.80/1000	$4.55/100	$31.00/1000
Meprobamate 400 mg	Equanil Wyeth	$.018/50 g.b. 192	$5.00/50 $43.75/500 $85.00/1000	$26.25/500 $51.00/1000	$22.31/500 $43.35/1000	$13.90/500	$34.12/1000
	Miltown Horner	$1.80/500 g.b. 192 (1)	$43.75/500				
	Generic Bell-Craig		$1.60/100 $6.25/500 $11.30/1000			$1.05/100 $3.90/500 $6.90/1000	
	Generic Empire		$1.60/100 $6.25/500 $11.30/1000				
	Generic Gilbert		$5.00/500 $9.75/1000	$4.00/500 $7.80/1000		$3.52/500 $6.86/1000	

(1) At the date of the Green Book (1961) Miltown was a product of Ayerst.

TRANQUILLIZERS

Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
Imipramine H.C.L. 25 mg	Tofraine Geigy	N.A.	$12.60/100	$7.56/100	$6.43/100	$7.56/100	$42.36/1000
Fluphenazine 1 mg 2 mg 5 mg	Moditen Squibb	N.A.	1 mg $19.00/100 2 mg $25.00/100 5 mg $43.00/100			$10.27/100	$97.88/1000 $150.00/1000
Levome-promazine 25 mg 50 mg	Nozinan Ponlenc	N.A.	25 mg $12.60/100 $63.00/500 50 mg $17.60/100 $88.00/500			$56.70/1000 $79.20/1000	$41.50/1000 $59.50/1000
Promethazine 25 mg 50 mg	Phenergan Ponlenc		25 mg $5.50/100 $27.50/500 50 mg $9.90/100			$23.00/1000 $41.00/1000	$17.50/1000 $31.50/1000
Oxazepam 10 mg 15 mg 30 mg	Serax Wyeth		10 mg $8.00/100 15 mg $10.00/100 30 mg $14.50/100			$18.71/500 $23.39/500 $33.93/500	$46.78/1000 $46.78/1000 $67.80/1000
Prochlor-Perazine 5 mg 10 mg 25 mg	Stemetil Ponlenc	N.A.	5 mg $7.00/100 $35.00/500 10 mg $9.00/100 $45.00/500 25 mg 12.00/100 60.00/500			$17.50/500 $22.50/500 $30.00/500	$21.00/1000 $30.00/1000 $38.00/1000

TRANQUILLIZERS

Generic name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital Edmonton	Price to Alberta Department of Health
Nortriptyline 25 mg	Aventyl Lilly	N.A.	$6.50/50 $13.00/100 $31.50/250	$3.90/50 $18.60/250		$36.72/1000	$36.28/1000 Lilly, July 14/65 10 mg-$28.80/1000 25 mg-$55.80/1000 $53.00/5000
Chlor-diazepoxide 5 mg 10 mg 25 mg	Librium Roche	N.A.	5 mg $9.00/100 $40.00/500 $76.00/1000 10 mg $12.00/100 $54.00/500 $102.00/1000 25mg $18.50/100 $83.00/500 $157.00/1000	5 mg $5.40/100 $24.00/500 $45.60/1000 10 mg $7.20/100 $32.40/500 $61.20/1000 25 mg $11.10/100 $49.80/500 $94.20/1000		$28.50/1000 $38.20/1000 $58.80/1000	$34.00/1000 $52.00/1000
	Protensin Elliott-Marion	N.A.	5 mg $8.50/100 /500 /1000 10 mg $10.85/100 /500 $97.50/1000 25 mg $18.00/100 /500 /1000			$29.75/1000 $31.50/1000 $54.25/1000	
	Bell-Craig						

TRANQUILLIZERS

Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital, Edmonton	Price to Alberta Department of Health
Amitriptyline H.C.L. 25 mg.	Elavil MS & D	NA	$12.50/100 $60.20/500			$6.75/100 $32.50/500	$47.50/1000
Trimipramine 25 mg 100 mg	Surmontil Ponlenc	NA	25mg: 12.60/100 63.00/500 100mg: 38.00/100			$3.50/100 $31.50/500 $57.00/1000	$45.00/1000 $135.00/1000
Desipramine H.C.L. 25 mg.	Pertoprane Geigy	NA	$13.20/100 $66.00/500			$7.92/100 $39.60/500	$56.50/1000
Diazepam 5 mg 10 mg	Valium Roche		5 mg $7.95/100 $67.92/1000 10 mg $12.90/100 $110.28/1000	5 mg $13.50/100 $113.20/1000 10 mg $21.50/100 $183.80/1000		$5.96/100 $50.99/1000 $9.68/100 $82.79/1000	$41.82/1000 $67.88/1000

DIABETES DRUGS

Generic Name	Brand Name	Manufacturer's Cost	List Price	Price to Retail Pharmacist	Price to Wholesaler	Price to University Hospital, Edmonton	Price to Alberta Department of Health
Tolbutamide 0.5 gram	Orivase Hoechst		$6.25/50 $59.40/500			$42.00/1000	$4.20/100 by tender
	Mobenol Horner		$6.25/50 $59.40/500			$42.00/1000	$4.20/100 by tender
	Canada Pharmacal					$11.75/1000	
	Generic Gilbert		$9.50/500 $18.25/1000				
	Generic Empire		$5.00/100 $23.00/500 $44.00/1000				
Chlor-propamide 250 mg	Diabinese Pfizer		$12.11/100 $57.00/500		$6.06/100 $28.50/500	$5.90/100 $28.24/500	$5.00/150
Phenformin H.C.L. 50 mg.	DBI-T.A. Arlington-Funk		$17.25/100	$10.35/100		$7.80/100	$5.89/100

APPENDIX E

1962

CHAPTER 61

An Act to amend The Alberta Pharmaceutical Association Act

(Assented to April 5, 1962)

HER MAJESTY, by and with the advice and consent of the Legislative Assembly of the Province of Alberta, enacts as follows:

1. The Alberta Pharmaceutical Association Act, being chapter 232 of the Revised Statutes, is hereby amended.

Section 2 amended

2. Section 2, clause (c) is amended
   (a) by striking out the word "or" at the end of subclause (i) and by adding the word "or" at the end of subclause (ii),
   (b) by adding immediately after subclause (ii) the following new subclause:
      (iii) in the Food and Drug Act (Canada) or the regulations thereunder;

New section 45

3. The following new section is added immediately after section 44:

Prescription by generic name

45. Where a prescription refers to a drug or drug combination by a brand name or a name other than its generic name, a pharmaceutical chemist, in dispensing the prescription, may use a drug or drug combination that is the generic or brand name equivalent of that named in the prescription unless the prescriber indicates otherwise
   (a) by designating the name of the manufacturer, or
   (b) by specifying that no equivalent is to be dispensed.

Coming into force

4. This Act comes into force on the day upon which it is assented to.

Printed by L.S. WALL, Printer to the Queen's Most Excellent Majesty,
Edmonton, Alberta, 1962

List of References

1. Report Concerning the Manufacture, Distribution, and Sale of Drugs; Restrictive Trade Practices Commission, Series, 24, Department of Justice, Ottawa, 1963.

a.	p.	178
b.	p.	466
c	p.	498
d.	pp.	426-427
e.	p.	302
f.	p.	300
g.	p.	519
h.	p.	432
i.	p.	314
j.	p.	197

2. Material Collected for Submission to the Restrictive Trade Practices Commission in the course of an Inquiry under section 42 of the Combines Investigation Act, Relating to the Manufacture, Distribution, and Sale of Drugs by the Director of Investigation and Research, Combines Investigation Act, Department of Justice, Ottawa, 1961. ("Green Book")

a.	p.	231
b.	p.	232
c.	pp.	152-202
d.	pp.	168-169
e.	pp.	169-170
f.	pp.	191-192
g.	p.	193
h.	p.	114
i.	p.	261
j.	p.	152
k.	p.	82
m.	pp.	261-262
n.	p.	91
o.	pp.	104-105; 261-262

3. Royal Commission on Health Services; Submission of the Province of Alberta, Edmonton, February 12, 1961.

a.	p.	92
b.	p.	93

4. Administered Prices: Hearings Before the Subcommittee on Antitrust and Monopoly of The Committee on the Judiciary of the United States Senate. (13 parts, numbered 14-26) Washington, D.C., 1960-1962.

a.	Part 20,	p.	11082
b.	Part 18,	pp.	10510-10518
c.	Part 18,	p.	10379
d.	Part 18,	p.	10254
e.	Part 24,	pp.	14167-14168
f.	Part 18,	p.	10418
g.	Part 22,	p.	12032
h.	Part 24,	pp.	450-451
i.	Part 14,	pp.	8285-8286
j.	Part 24,	pp.	13972-13973
k.	Part 14,	p.	8215
m.	Part 18,	pp.	10476-10477
n.	Part 21,	pp.	11608-11626
o.	Part 19,	pp.	10615-10616
p.	Part 14,	p.	7993
q.	Part 18,	p.	10372
r.	Part 18,	p.	10398

5. Administered Prices--Drugs. Report of the Committee on the Judiciary of the United States Senate, made by the Subcommittee on Antitrust and Monopoly, 87th Congress, First Session, Washington, D. C. 1961.

a.	p.	31
b.	pp.	126-137
c.	p.	18
d.	p.	82
e.	p.	99
f.	p.	101
g.	pp.	235-241

6. Submission to the House of Commons Special Committee on Drug Costs and Prices by the Pharmaceutical Manufacturers Association of Canada, at Ottawa, Ontario, June, 1966.

a.	Appendix O
b.	Page 2-1
c.	Page 7-3
d.	Page 2-3
e.	Page 2-1
f.	Page 5-5
g.	Page 14-2

7. Special Committee on Drug Costs and Prices--Minutes of Proceedings and Evidence. House of Commons, First Session, Twenty-Seventh Parliament, Ottawa, 1966.

a.			
b.	Part 8,	pp.	538-546
c.	Part 1,	p.	30
d.	Part 8,	p.	459
e.	Part 13,	p.	942
f.	Part 15,	p.	1066
g.	Part 14,	p.	1020
h.	Part 11,	p.	791
i.	Part 10,	pp.	696-703; Part 26, pp. 1738-1739
j.	Part 5,	p.	227
k.	Part 9,	pp.	550-551
m.	Part 5,	p.	240
n.	Part 2,	p.	29
o.	Part 17,	p.	1184
p.	Part 5,	p.	190
q.	Part 5,	p.	171
r.	Part 5,	p.	173
s.	Part 5,	p.	216
t.	Part 3,	p.	59
u.	Part 20,	p.	1370
v.	Part 20,	p.	1348
w.	Part 20,	p.	1335
x.	Part 20,	p.	1359
y.	Part 20,	pp.	1361-1362
z.	Part 20,	p.	1362
aa.	Part 20,	p.	1365
bb.	Part 20,	p.	1366
cc.	Part 20,	p.	1367
dd.	Part 10,	p.	599
ee.	Part 10,	p.	657
ff.	Part 11,	p.	768
gg.	Part 20,	p.	1355
hh.	Part 11,	p.	767
ii.	Part 10,	p.	690

kk.	Part 3,	p.	75
mm.	Part 19,	p.	1302
		p.	1321

8. Gilbert Burck: "U.S. Oil--A Giant Caught in its Own Web," Fortune April, 1965, p. 114.

9. Drug Industry Antitrust Act: Hearings Before the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary, United States Senate, Eighty-Seventh Congress, First Session, Pursuant to S.Res. 52 on S. 1552, Washington, D.C., 1961-1962 (7 Parts)

a.	Part 1,	p.	318
b.	Part 4,	p.	2056
c.	Part 7,	pp.	3301-3310
d.	Part 4,	p.	2410
e.	Part 1,	p.	325
f.	Part 5,	p.	2938
g.	Part 1,	p.	329
h.	Part 5,	p.	1377
i.	Part 4,	pp.	2058-2059

10. H. B. Steele: "Monopoly and Competition in the Ethical Drugs Market," Journal of Law and Economics, October, 1962, pp. 131-163.

11. H. B. Steele: "Patent Restrictions and Price Competition in the Ethical Drugs Market," Journal of Industrial Economics, July 1964, pp. 198-223.

12. H. B. Steele: "The Fortunes of Economic Reform Legislation: The Case of the Drug Amendments Act of 1962," American Journal of Economics and Sociology, January, 1966, pp. 39-51.

13. Charles E. Silberman, "Drugs: The Pace is Getting Furious," Fortune, May, 1960, p. 276.

14. Brian Inglis, Drugs, Doctors and Diseases, London, 1965, p. 27.

15. Brief to the Special Committee of the House of Commons on Drug Costs and Prices, by Hoffmann-LaRoche, Limited, October, 1966.

a.	pp.	22-23
b.	p.	24
c.	p.	55
d.	p.	58
e.	p.	46
f.	p.	43

16. Brief to the House of Commons Special Committee on Drug Costs and Prices, Submitted by The Consumers' Association of Canada, Ottawa, November, 1966, p.8.

17. D. S. Watson: Economic Policy--Business and Government, Boston 1960, p. 334.

18. M. Fainsod, L. Gordon, and J. C. Palamountain, Jr.: Government and the American Economy, New York, 1959, pp. 560-565.

19. Adam Smith: Wealth of Nations (Modern Library Edition), p. 112.

20. F. Brown, "The Pharmaceuticals Industry," in Glover and Lagai (editors), The Development of American Industries, New York, 1959, pp. 332-355.

21. Clair Wilcox, Public Policies Toward Business, Homewood, Illinois, 1960. p. 422.

22. H. Steele and G. Rimblinger, "An Economic Interpretation of the Spatial Distribution of Physicians in the United States, "Southern Economic Journal, July, 1963, pp. 1-12.

23. H. Steele and G. Rimlinger, "Income Opportunities and Physician Location Trends in the United States, "Western Economic Journal, Spring 1965, pp. 182-194.

24. L. J. Robbins, "Pharmaceutical Patents in Foreign Countries," Journal of the Patent Office Society, Washington, D.C., Vol. 37, 1955.